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Research for Action

Understanding and Controlling Tuberculosis in India



World Health Organization
Regional Office for South-East Asia
New Delhi

This report was prepared by Thomas R. Frieden and Jim Mullins.

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This publication is dedicated to patients and health care workers who work sincerely to ensure accurate diagnosis and effective treatment of tuberculosis in both public and private sectors.

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Contents

Foreword	`
Executive Summary	vi
The Origins of DOTS	1
Key findings and implications for action	
The five principles of DOTS	
Tuberculosis in India	11
Health impact	
Economic impact	
HIV and TB	
Multidrug-Resistant Tuberculosis (MDRTB)	
Key findings and implications for action	
TB Diagnosis and Treatment in India	2
The National Tuberculosis Programme (NTP)	
"Health-seeking behaviour of chest symptomatics"	
Key findings and implications for action	
The RNTCP and DOTS	3:
Current accomplishments	
Key findings and implications for action	
Strengthening the RNTCP	4
Involvement of the private sector	
Tuberculosis Research Centre – ACT and private practition	ners
Mahavir Trust Hospital - key lessons	

	53
Involvement of NGOs	33
Self-Employed Women's Association (SEWA)	
The Nehru Nagar TB Center	
Sivananda Rehabilitation Home – involvement of leprosy programmes	
Key findings and implications for action	
Conclusion: The Importance of Research	65
	68
References	00

Foreword

On March 26, 1997, India formally launched the Revised National Tuberculosis Programme (RNTCP), with phased coverage in various States throughout India.

The RNTCP, which employs the WHO-recommended treatment strategy of DOTS – Directly Observed Treatment, Short-course – is about people. It is about helping health workers accurately diagnose and reliably cure patients with tuberculosis. It is about making the health system accountable for outcomes. It is, above all, about putting the patient first, and making him or her the VIP of tuberculosis control activities.

In late 1998 and early 1999, the RNTCP began rapid expansion, and India now has the second largest DOTS programme in the world, having served more than 200,000 TB patients and saved more than 35,000 lives.

The RNTCP has initiated fruitful partnerships with private and non-governmental sectors, some of which are profiled in this document. The promise of these partnerships has made it clear that the government cannot implement the RNTCP alone. There must be a shared commitment from private practitioners and non-governmental organizations. In addition, there must be a strong research base that builds on India's long and distinguished tradition of innovative investigations in the field of tuberculosis.

This is no time for complacency. Every day in India, more than 1,000 people die from tuberculosis. The HIV epidemic and the risk of multidrug-resistant tuberculosis threaten to make the tuberculosis crisis even worse.

Effective implementation of DOTS through the RNTCP can save hundreds of thousands of lives in India. Every patient who is cured stops spreading TB. Each life saved represents a child, mother, or father who will go on to live a longer, productive, TB-free, life.

Tuberculosis is a curable disease. Working together, we will win the battle against the tuberculosis epidemic.

Dr. Uton Muchtar Rafei Regional Director

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Regional Office for South East Asia World Health Organization

Executive Summary

Unless urgent action is taken, more than 15 million people – more than 4 million of them in India alone – will die from tuberculosis in the next decade. Yet tuberculosis can be cured in nearly all cases. Directly Observed Treatment, Short-course (DOTS) – which is based on research done in India – has become the accepted standard for the diagnosis, treatment, and monitoring of tuberculosis worldwide. DOTS, which cures 8 out of 10 patients treated, has now been implemented in more than 110 countries in response to the growing threat of tuberculosis. Ironically, although the principles of DOTS were largely discovered in India, until recently, DOTS had not been applied widely in the country. DOTS is a classic example of research findings not being applied where they are most needed – and where they were discovered!

India accounts for nearly 30 per cent of all tuberculosis cases in the world today, and more adults in India die from TB than from any other infectious disease.

The economic burden caused by tuberculosis in India is enormous. Every year, tuberculosis costs India more than \$3 billion (Rs. 13,000 crore). In addition, every year, TB patients spend more than Rs. 645 crore (US\$180 million) on private TB care. Tuberculosis does not merely reflect socioeconomic status – tuberculosis perpetuates and exacerbates poverty.

The problems of HIV and multidrug-resistance will make the tuberculosis epidemic in India much worse unless urgent action is taken. Fortunately, DOTS is as effective among HIV-infected TB patients as among those who are HIV negative.

The economic burden caused by tuberculosis in India is enormous. Every year, tuberculosis costs India more than \$3 billion (Rs. 13,000 crore). In addition, every year, TB patients spend more than Rs. 645 crore (US\$180 million) on private TB care

And the widespread use of DOTS can prevent multidrugresistance. It is essential that DOTS be rapidly and effectively implemented before multidrug-resistant tuberculosis and HIV become more widespread.

Diagnosis and treatment of tuberculosis in India

Patients with symptoms of TB in India seek care promptly – but in both public and private systems, they are neither reliably diagnosed nor effectively treated. Where services are better, patients seek care even more promptly. In one systematic evaluation, patients with cough sought care, on average, I I days after the onset of symptoms. However, despite 8 encounters with the health system and expenditure of I-6 months' wages, only one third of patients with symptoms of TB had undergone even a single sputum examination for tuberculosis! Even for patients who are eventually diagnosed, successful treatment of tuberculosis is the exception rather than the norm in both public and private sectors.

The behaviour of patients does not need to be changed – the health system's response to this behaviour must improve

The behaviour of patients does not need to be changed – the health system's response to this behaviour must improve. In both public and private health care systems, health workers need to "Think TB" and ensure that every adult patient is asked whether or not they have cough for 3 weeks, and, if they do, that they undergo 3 sputum examinations in a good quality laboratory.

The Revised National Tuberculosis Programme (RNTCP)

For too long, tuberculosis has been seen as a natural calamity about which nothing can be done.

In 1993, India adopted and tested a strategy known as the Revised National Tuberculosis Control Programme (RNTCP).

The RNTCP is an adaptation of the DOTS strategy, which Indian research help to establish, to the Indian context. In RNTCP pilot areas, diagnostic practices improved and cure rates more than doubled. By mid-1999, India had the second largest DOTS programme in the world, and more than 200,000 patients had been treated. This intervention has already saved more than 35,000 lives, and has the potential to save millions of lives over the next decade.

Forty years after the discovery of the principles of DOTS in India, DOTS is being applied on a mass basis in the country. Maintaining the momentum in order to achieve national coverage in a phased manner, while maintaining the quality of services, will require constructive commitment from all sectors. In areas where the RNTCP is in operation, the availability of free, curative services should be publicized widely.

At all levels, the positive achievements and successes of the programme should be emphasized – India is showing its own citizens and the world that it can reliably diagnose and treat tuberculosis in the community on a mass basis.

Strengthening the RNTCP

For India's RNTCP to succeed, there must be a shared commitment from both within and outside the government. In addition, there must be meaningful and ongoing research and data analysis.

The private health sector is the first point of contact for most TB patients in India. The RNTCP offers a unique opportunity for collaboration between public and private sectors. Several models of successful collaboration already exist.

In a joint effort of the government and the private sector, the Mahavir Trust Hospital, a nonprofit specialty hospital in the city

India is showing its own citizens and the world that it can reliably diagnose and treat tuberculosis in the community on a mass basis

of Hyderabad, Andhra Pradesh, has involved individual private practitioners who refer patients and provide space and staff for treatment observation. The project has demonstrated that collaboration between the public and private sectors is both feasible and cost effective.

The RNTCP also needs broad participation by community-based, non-governmental organizations. The Self-Employed Women's Association (SEWA), based in Ahmedabad, is an organization of nearly a quarter of a million women workers in the unorganized sector in India. SEWA launched a pilot TB project in the northern zone of Ahmedabad in which neighbourhood DOTS providers disseminate information about TB in the community, identify suspected TB patients and refer them to microscopy centres, provide treatment observation, ensure follow-up sputum examination at prescribed intervals, and work closely with TB patients to ensure complete treatment.

Cooperation between public and private sectors is often most successful when there is an institutional intermediary to bridge the gap in trust and communication

Each community has strengths, and these strengths can be enlisted to support effective diagnosis and treatment of tuberculosis patients. But in each community, the strengths are likely to be different – just as individuals are each unique, so is each community. In some communities, strong nongovernmental organizations can play an essential role in tuberculosis control. In others, private, trust, or corporate health institutions can serve as key intermediaries between the government TB programme and private physicians. Cooperation between public and private sectors is often most successful when there is an institutional intermediary to bridge the gap in trust and communication. NGOs and private physicians are often closer to, and more trusted by, TB patients. These strengths can be harnessed to extend the reach and improve the efficacy of DOTS - but only with careful safeguards to ensure that diagnosis and treatment are correct, convenient, and free of charge.

Successful collaboration requires training, ongoing communication, monitoring, and supervision. Expectations on the part of all parties need to be explicitly stated at the outset, and two-way feedback needs to be frequent and frank. Successful projects do not just happen — they require nurturing, communication, and careful monitoring.

Policy-makers should provide a framework for coordination on DOTS, but allow local flexibility within this framework. Local programme managers should analyze and evaluate resources available in their community. The goal is to identify facilities and means by which patients may be diagnosed more promptly and can receive observed treatment more conveniently. Nongovernmental organizations should assess their strengths and potential contribution to effective diagnosis and treatment of tuberculosis. Those with a strong presence in the community can play an important role in control of the disease.

Private physicians should coordinate with the governmental TB programme in their area for diagnosis, treatment, and monitoring. No patient should ever be started on anti-TB treatment unless a full course of treatment can be ensured.

The Importance of Research

DOTS has evolved through decades of research – much of it done in India – and it must continue to evolve as it adapts to local situations and emerging scientific data. The RNTCP must maintain a strong programme of evaluation and operational research that provides data to better define the problems of TB control and to test interventions to solve these problems.

Operational research provides programme managers the data and tools they need to analyze and continuously improve the services they offer. The goal is to improve diagnosis and Successful projects do not just happen – they require nurturing, communication, and careful monitoring

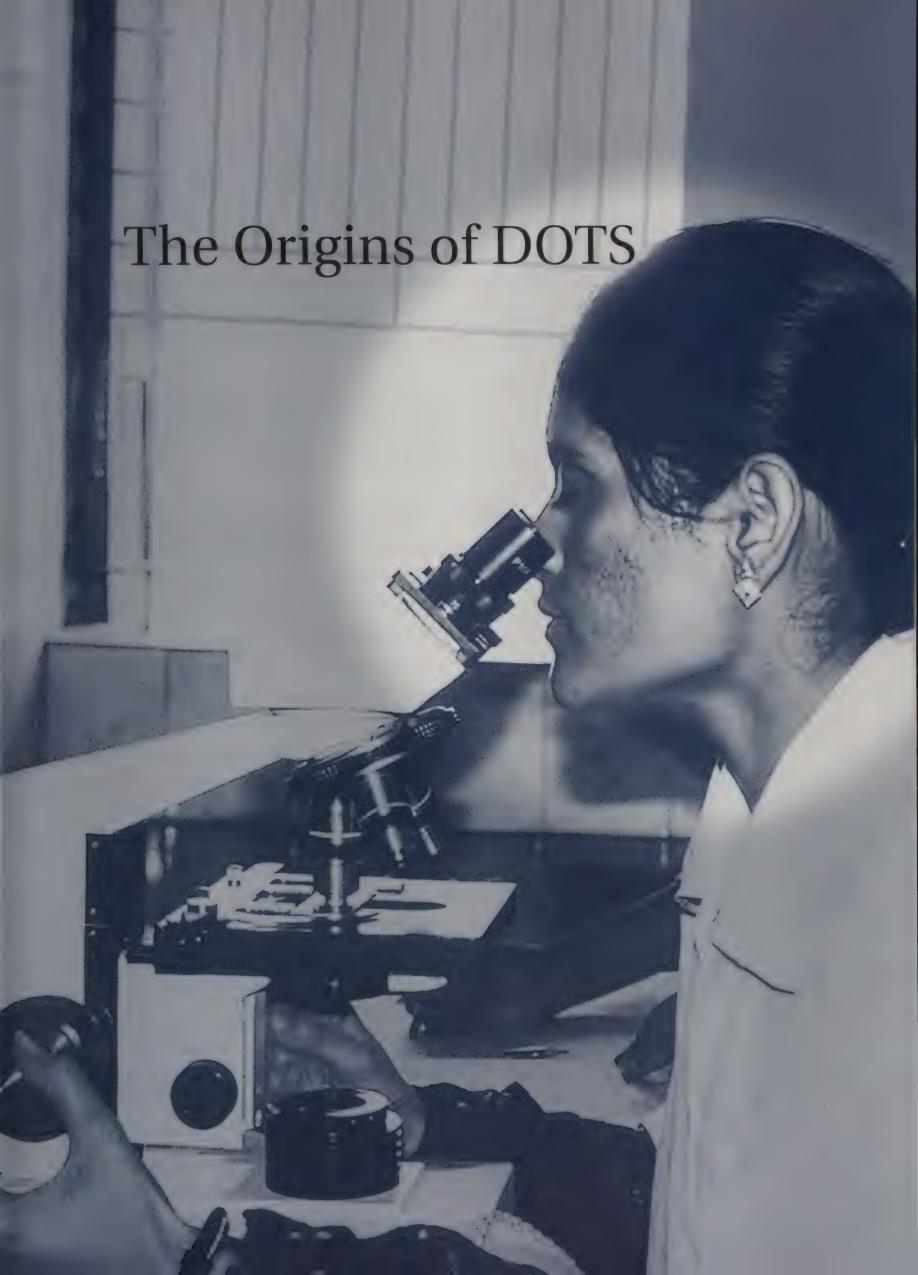
treatment of TB patients by translating the results of research into policy and practice.

But world-class research is not enough. Researchers must

make every effort to ensure that their findings are promptly translated into more rapid and accurate diagnosis and more reliable and effective treatment of TB patients. Programme managers, by fostering an atmosphere of enquiry and analysis, can identify services which need improvement, as well as the means to improve these services. Policy makers need to be aware of research findings and of the implications of these findings for programme decisions. And international agencies need to ensure that appropriate research is supported and that relevant findings are provided to decision-makers so that the implications of these findings can be incorporated into practice.

Not only can the
RNTCP save millions of
lives and hundreds of
millions of dollars, it can
also promote a culture in
which decisions are
based on data

India's Revised National Tuberculosis Control Programme has important implications for health and development. Not only can the RNTCP save millions of lives and hundreds of millions of dollars, it can also promote a culture in which decisions are based on data. This can provide a solid and lasting foundation for continuous improvement in all of India's health services.



DOTS – Directly Observed Treatment, Short-course – has become the accepted standard for the diagnosis, treatment, and monitoring of tuberculosis worldwide. In 1997, the Director-General of the World Health Organization declared that "The DOTS strategy represents the most important public health breakthrough of the decade in terms of lives which will be saved."

But DOTS is not new. In fact, the essential principles of DOTS are a product of India's long and distinguished tradition of tuberculosis research.

The essential principles of DOTS are a product of India's long and distinguished tradition of tuberculosis research

From 1955 to 1958, India conducted a national survey which documented the burden of tuberculosis and the urgent need for services. In the 1960s, studies at the National Tuberculosis Institute in Bangalore documented the efficacy and feasibility of case detection by sputum microscopy. In the 1950s and 1960s, studies at the Tuberculosis Research Centre in Chennai demonstrated the efficiency and safety of home treatment of tuberculosis, the effectiveness of intermittent chemotherapy, and the necessity and feasibility of direct observation in the community.

At that time, the standard treatment for tuberculosis in India and throughout the world called for isolation of TB patients in sanatoriums, away from the general population.

"Unfortunately, India had only 40 thousand sanatorium beds in the whole country, and there were 10 million cases of TB," says Dr. C.V. Ramakrishnan, retired Deputy Clinical Director of the Tuberculosis Research Centre. "It was obvious that we wouldn't be able to treat all cases in institutions, so the only feasible method was to treat in homes.

"In France, they believed that you could take the TB treatment to every home. That wasn't possible in India, so

the idea was to set up a clinic where patients could come and collect their drugs. At first, we tried giving patients a week's worth of daily doses at a time. The problem was that collection was not commensurate with consumption, and a large percentage of the patients were not taking the drugs. There were a lot of defaulters.

"So the question was, how to handle the defaulters? It was decided that it would be better to give the drugs under supervision than by self-administration."

This use of supervised treatment – now known as directly observed treatment – in which patients are observed taking their anti-tuberculosis medications, was shown to be essential in India.

Intermittent treatment, in which the medications were given two or three times a week, rather than daily, was also first shown to be effective at the

Tuberculosis Research Centre.² The slow-growing nature of *Mycobacterium tuberculosis* – with a doubling time of 18 to 24 hours, compared with 12 to 20 minutes for most bacteria – makes this possible.

"Studies were done that showed that intermittent treatment would not affect the efficacy of the drugs," says Dr.
Ramakrishnan. "So why not apply this to the treatment of patients? It was tried in Bangalore and Delhi without supervision, but they had only a fifty to sixty percent success rate. Our impression was that this was not due to a lack of efficacy of the drugs, but to patient failure, or clinic failure.

That is, no one was paying attention to whether the person actually took the drug. So direct supervision was absolutely necessary."



Dr. C.V. Ramakrishnan, retired Deputy Clinical Director of the Tuberculosis Research Centre

The feasibility and importance of case finding by microscopy—in which the sputum of suspected tuberculosis patients is examined for the presence of *Mycobacterium tuberculosis*—is one of the most important research findings made in India in the 1960s, says Dr. Ramakrishnan, and one of the most important components of DOTS.

"In the past the doctors have mostly based their diagnosis on x-ray because good sputum exams were not available to them," he says. "But when you use x-ray as a diagnostic tool, you might treat 10 patients for TB based on x-ray results, but only three will actually have the disease. The shadow on the x-ray might be lots of things. Proof positive is the demonstration of bacilli in the sputum. If you treat the 90 percent of sputum-positive cases who come in for care, you remove the pool of infection. And making the change from x-ray to microscopy is something that you can do anywhere in the world."

After the principles of DOTS were developed in India, Dr. Karel Styblo, scientific director of the International Union Against Tuberculosis and Lung Disease (IUATLD), combined these components into a powerful treatment system that ensured monitoring, supervision, and accountability for every patient. Styblo showed that this system could provide effective TB treatment that would be affordable for developing countries.

The new strategy was to use a combination of anti-TB drugs – called short-course chemotherapy – on a large scale. By using the drugs isoniazid, rifampicin, pyrazinamide and streptomycin or ethambutol together, it was possible to cut treatment time in half, thereby encouraging more TB patients to successfully complete their treatment. Many of the controlled clinical trials establishing the efficacy of short-course treatment for various forms of tuberculosis were done at the Tuberculosis Research Centre, Chennai.

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In the programme, detection of tuberculosis is based on the active search for TB patients among outpatients at health facilities, rather than in the community. Most patients with active tuberculosis seek care, and the few who don't are less likely to complete treatment. Styblo found that well-organized outpatient chemotherapy, especially if provided free of charge, attracted symptomatic cases from far and wide. This had been well documented by a study from the National Tuberculosis Institute in Bangalore in the early 1960s, and has proven to be true, in India and throughout the world.



TB patient, Orissa, India

Another important element of the new strategy was an innovative recording and reporting system — simple enough to be completed easily, but detailed enough to provide useful information for ongoing evaluation of the progress of both the patient and the programme. This new recording and reporting system makes health workers accountable for directly observing that TB patients take their medicines, making it unnecessary to hospitalize most TB patients during treatment.

To the surprise of many, cure rates in Tanzania, where Styblo first tested his system, increased from 30 and 40 per cent to 80 per cent. Even more impressive, these results were achieved for a very small additional cost. It was calculated that the average cost of curing one patient – including transportation, infrastructure, and staff costs – was under US \$200. In 1993, the World Bank published an important analysis of various health interventions which found that DOTS was among the most cost-effective, on a par with childhood immunization. With increased use of this strategy, costs of key inputs such as microscopes and drugs have decreased, and it can now cost \$20 or less to cure a patient.

The World Health Organization formally adopted DOTS as its recommended strategy for global TB control. DOTS, which can cure 8 out of 10 TB patients, has been implemented in more than 110 countries around the world as a response to the growing threat of tuberculosis.

African countries such as Malawi, Mozambique, and Tanzania have documented TB cure rates of 86 percent to 90 percent through the use of DOTS, despite the burdens of poverty, HIV, and a daunting lack of resources. Even countries in the midst of war, including Nicaragua and Mozambique, were able to achieve excellent results with DOTS. DOTS has been associated with a substantial decline in tuberculosis in Cuba.⁵

DOTS is a classic example of research findings not being applied where they are most needed – and where they were discovered! Directly observed treatment, eventually with short-course treatment, was implemented in Beijing, China. Smear-positive tuberculosis decreased from 127 per 100,000 in 1979 to 16 per 100,000 in 1990, a decrease of 17 percent annually.⁶ More recently, a World Bank-assisted project in China has had remarkable success. More than three million patients have undergone sputum examinations, and more than 515,000 smear-positive patients have been treated, with cure rates of more than 93 percent. The programme in China currently covers a population of 800 million. ^{7,8}

In the United States, the use of DOTS led to a marked reduction in case rates in Baltimore, despite a high rate of HIV infection. In New York City, where, by 1991, approximately half of all tuberculosis patients were HIV infected and one in five had multidrug-resistant tuberculosis, DOTS resulted in a rapid decrease in both tuberculosis (by two thirds) and multidrug resistance (by more than 90%). IO, II

In South-East Asia, Bangladesh has had excellent success with the DOTS programme, with coverage of nearly the entire country and cure rates of about 80 percent.¹²

DOTS has now been officially adopted by the Government of India as part of its Revised National Tuberculosis Control Programme (RNTCP).

"Some people believe that DOTS has been one of India's best exports," says Dr. Ramakrishnan. "It has been sent out into the world, tested, proven, and now it has come back to us, better than ever."

Key Findings and Implications for Action

India has given the world much of its knowledge about diagnosis and treatment of tuberculosis. Key findings from the Tuberculosis Research Centre, Chennai, and the National Tuberculosis Institute, Bangalore have changed practices all over the world. Application of these findings in other countries has led to sustained decreases in tuberculosis. These findings show that:

- World-class research is not enough. Researchers must make every effort
 to ensure that their research is converted into action that their findings
 improve practices. DOTS is a classic example of research findings not
 being applied where they are most needed and where they were
 discovered! Research should be rapidly translated into more prompt and
 accurate diagnosis and more reliable and effective treatment of TB patients.
- Programme managers have a responsibility to support research. Fostering
 an atmosphere of enquiry and analysis strengthens programmes by
 continuously identifying areas which need improvement, as well as the
 means to improve the programme in these areas.
- Policy makers need to be aware of research findings and of the implications of these findings for programme decisions.
- International agencies need to ensure that appropriate research is conducted and that relevant findings are provided to decision-makers so that the implications of these findings can be incorporated into practice.

The five principles of DOTS

DOTS (Directly Observed Treatment, Short-course) is a comprehensive strategy for systematic diagnosis and effective treatment of tuberculosis. Health workers counsel and observe their patients swallowing each dose of a powerful combination of medicines, and the health services monitor the patients' progress until each is cured. Political and financial commitment and a dependable drug supply are essential parts of the DOTS strategy.



I.Case detection primarily by microscopic examination of sputum of patients presenting to health facilities

Microscopy – not X-ray – must be the primary tool to diagnose tuberculosis. Only bacteriologic examination can confirm whether or not TB bacilli are present. Resources should first be directed toward identifying sputum smear-

positive cases for treatment, as these people are the sources of infection. X-ray is a complementary tool when sputum smears are negative. Tuberculosis patients commonly seek care, but are not promptly diagnosed – the challenge is to improve the performance of the health system.

2. Adequate drug supply

The establishment of a dependable, high-quality supply of anti-TB drugs throughout the health system is an essential part of the DOTS strategy. The correct combination and dosage of anti-TB medicines — known as short-course chemotherapy — must be used for the right length of time. These drugs — which include isoniazid, rifampicin, pyrazinamide, streptomycin and



ethambutol – provide a knock-out punch to kill the TB bacilli. They are typically administered for six or eight months in accordance with WHO treatment guidelines.



3. Short-course chemotherapy given under direct observation

An uninterrupted supply of drugs is a necessary but not a sufficient condition for tuberculosis control. DOTS succeeds because it makes the health system — not the patient — responsible for achieving a cure. This is critical, as most TB patients start to feel better after just a few weeks of medication and often stop taking their pills. Yet it

takes at least six months to rid the body of TB bacilli. With DOTS, patients are observed swallowing their medicines by a health worker or trained volunteer. Treatment observers support patients until they are cured.

Treatment observation is especially critical during the first two months of treatment when the patient may be seriously ill, at risk of acquiring drug resistance, and may spread the disease to others. During this phase, the number of tuberculosis bacteria in the body is very high, and any missed doses increase the risk of treatment failure and relapse. Patients who do not keep their appointments with the health worker must be immediately contacted and helped to resume treatment.

There can be flexibility and innovation in observing treatment, provided that the observer is accountable to the health services and accessible to the patient. Observation should be a convenient service to patients and a symbol of a government's commitment to ensure cure and control of tuberculosis.

4. Systematic monitoring and accountability for every patient diagnosed

TB patients must be provided complete treatment and be monitored to ensure cure. Sputum is examined during and at the end of treatment to ensure that a patient is free of TB bacilli. The recording and reporting system rigorously monitors and evaluates progress made treating and curing each TB patient. Through analysis of each group of patients, this system enables health services to quickly identify districts and communities not achieving 85 percent cure rates and intervene with additional support and training.





5. Political will

Governments and other partners must be financially committed to long-term TB control, ensuring that all TB patients have free access to treatment. TB control should be integrated into the existing health system and supported with leadership from a central TB unit. A well-supported National TB Programme will have a programme manual, a training programme, a plan of supervision, and a development plan.





Health impact

Tuberculosis is an infectious disease caused by a bacillus – *Mycobacterium tuberculosis* – that spreads through the air when untreated TB patients cough. Left untreated, a single person with active TB can infect 10 to 15 others each year, creating a self-perpetuating pool of infection.

Someone in the world is infected with TB every second.

Seven to eight million people become sick and two million die from it each year.

Tuberculosis has existed in India since the earliest days. In I500 BC, the Rig Veda described the illness as *Rājayakṣma*, king of diseases. Today, India accounts for nearly 30 per cent of all tuberculosis cases in the world, a figure that is likely to increase as India's population grows and the HIV epidemic progresses.¹³

COUNTRY	Population (millions)	Total TB Cases in (thousands, pe	estimated ncidence er 100,000 per year	Estimated new infectious case	v New es infectious cases treated under DOTS, 1997
India	960,178	1,799	187	805,000	7,708
China	1,243,738	1,402	113	630,000	147,905
Indonesia	204,323	583 (4.45)	285	262,000	19,492
Bangladesh	122,013	300	246	135,000	25,871
Pakistan	143,831	261	181	117,000	and a
Nigeria	118,369	253	214	110,000	11,235
Philippines	70,724	222	314	100,000	3,190
South Africa	43,336	170	392	69,000	4,146
Russia	147,708	156	106	70,000	660
Ethiopia	60,148	156	260	66,000	15,753

Source: Dye C, Scheele S, Dolin P, Pathania V, Raviglione MC. Global burden of tuberculosis. JAMA; 292: 677-686.

Most adults in India have been infected with the tuberculosis bacteria. In a 1997 review, Prevalence and Incidence of Tuberculosis Infection and Disease in India, A.K.

Chakraborty found that tuberculosis is common over all of India, in both rural and urban areas. About 38 percent of people of all ages are infected with the disease, while infection among males above 40 years of age runs as high as 70 percent.



According to the 1999 World Health Report, the burden of tuberculosis in India is 36 times more than leprosy, 13 times more than malaria, 2.5 times more than tropical diseases, and 35% more than HIV/AIDS.¹⁵

More adults in India die from TB than from any other infectious disease – one every minute and more than 1,000 every day – a grim statistic that has changed little over the past two decades.

Every year, 2 million people in India develop the disease, half of whom — more than 2,000 patients every day — have infectious and often fatal tuberculosis. Prevalence of the disease is more than twice the incidence, indicating a failure of current treatment programmes and a pooling up of previous cases. Unless promptly and effectively treated, these patients will infect succeeding generations and the cycle of infection, disease, and death from tuberculosis will continue.

Economic impact

The burden of suffering caused by tuberculosis in India is enormous. TB is one of India's biggest public health problems – a problem that India can ill-afford.

Tuberculosis and its spread remind us that we are all connected by the air we breathe.

Although sometimes considered a disease of slums and ghettos, affecting only the socially disadvantaged, tuberculosis can in fact affect anyone – from remote villages to bustling urban centers. Those infected are disproportionately young adults in the most productive years of their lives, often the primary wage earners of their families.¹⁶

TB is a disease that impoverishes families and undermines economic development.¹⁷ The direct and indirect economic costs of the tuberculosis epidemic cost India at least \$3 billion (Rs. I 3,000 crore) each year.

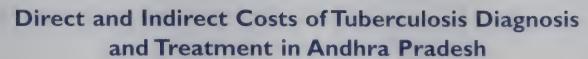
TB is one of India's biggest public health problems – a problem that India can ill-afford

In a 1997 study conducted in Tamil Nadu, ¹⁸ researchers at the Tuberculosis Research Centre in Chennai found that an average patient suffering from tuberculosis incurs a total loss of Rs.3469 (US\$ 99) while shopping for diagnosis and treatment. For a daily wage laborer who might hope to earn the equivalent

US\$ 200-400 per year, this is a prohibitive sum — equivalent to 3-6 months of wages. This study indicates that tuberculosis may cause 300,000 children to become orphans, and 100,000 Indian women to be rejected by their families each year.

In their study, Mapping of TBTreatment Providers at Selected Sites in Andhra Pradesh State, India, Ramana et al. ¹⁹ found that, on average, rural tuberculosis patients spent Rs 1000 (\$30) per month on TB diagnosis and treatment, while urban patients spent Rs 500 (\$15) per month (see figure). This almost invariably resulted in indebtedness and mortgage of valuables.

The World Health Organization estimates that TB patients in India together spent more than Rs. 645 crore (\$180 million) on private TB care in 1997.²⁰





Indian workers with tuberculosis lost an average of 83 work days because of the disease, 48 of which were lost while shopping for diagnosis. Considering that two million new cases are reported annually in India, the national loss per year works out to 166 million lost work days, at a cost of about \$200 million (Rs. 694 crore). In addition, the debts incurred by patients because of tuberculosis amounted to \$120 million (Rs. 416 crore). ¹⁷

TB kills more women of reproductive age than all causes of maternal mortality combined, 15 and it may create more orphans than any other infectious disease. Nearly one third of female infertility in India is caused by tuberculosis. 22

Indian women who suffer from TB face special constraints. They tend to neglect their illness due to household

responsibilities until they become too sick to attend to their normal duties. They are often dependent on others to get necessary medical attention.

There is also still a social stigma attached to TB. Sixty-nine percent of rural females interviewed by TRC researchers were reluctant to discuss their illness with neighbours.

The indirect impact of TB on children is considerable. Two thirds of the women interviewed in the Tamil Nadu study said that they were unable to look after the needs of their children because of TB. Nearly one-fifth of the schoolage children of TB patients either left school or took up employment to help support their families.

A successful DOTS programme could have substantial economic benefits for India

A successful DOTS programme could have substantial economic benefits for India. In his 1996 study, *The Potential Economic Benefits of the DOTS Strategy Against TB in India*, R.H. Dholakia of the Indian Institute of Management, Ahmedabad, divided these benefits into two broad categories.¹⁷

Direct, tangible economic benefits of DOTS would include:

- reduction in the incidence and prevalence of TB, which improves the efficiency and productivity of workers by reducing their forced absenteeism on account of ill health;
- TB deaths averted, which adds to the productive capacity of the economy; and
- release of the hospital beds currently occupied by the TB patients.

In addition, DOTS would enhance India's social welfare through:

- reduced suffering of TB patients,
- quicker and surer cure from the disease,
- lives saved and disability reduced for dependents and non-workers suffering from TB,

- poverty alleviation, and
- the benefits of living in a more healthy society.

HIV and TB

The Human Immunodeficiency Virus (HIV) has spread across India since the first cases of HIV infection were diagnosed in Bombay and Madras in 1986. WHO estimates that, by 1999, at least 3 million, and possible as many as 5 million people in India are infected with HIV, the virus that causes AIDS. That makes India the home of more HIV-positive individuals than any other country in the world. ¹⁵

Because the Human Immunodeficiency Virus breaks down the immune system and makes patients highly susceptible to TB, HIV will have a major impact on the TB epidemic in India. In some countries in Africa, the HIV epidemic has more than doubled or tripled TB cases.

Infection with HIV is the most potent known risk factor for progression to active tuberculosis among adults. Conversely, tuberculosis hastens the development of AIDS in HIV-infected persons. Individuals who are not HIV-infected and who become infected with Mycobacterium tuberculosis have approximately a 10 percent lifetime risk of developing active tuberculosis, compared with a risk of 60 percent or more in persons infected with both HIV and Mycobacterium tuberculosis. The risk of tuberculosis infection progressing to active tuberculosis is estimated to be 8 percent per year in an HIV-positive person, as opposed to a lifetime risk of 10 percent in an immunocompetent person. This is particularly important in India where it is estimated that more than half of the adult population harbors Mycobacterium tuberculosis infection.

In a developing country like India, the potential extra burden of new tuberculosis cases attributable to HIV is staggering and

Because HIV breaks down the immune system and makes patients highly susceptible to TB, HIV will have a major impact on the TB epidemic in India

could overwhelm already stretched tuberculosis budgets and support services.

The incidence of HIV seropositivity among patients admitted to the tuberculosis wards of a large public hospital in Bombay increased from 2% in 1988 to 16% in 1998.²⁷ Among Indian patients who are HIV positive, tuberculosis is by far the most common opportunistic infection. A 1994 study showed that 61 percent of all HIV-positive patients in India had tuberculosis at some point in the course of their HIV disease.²⁸

One of the most worrisome aspects of the interaction between HIV and TB is that strains of multidrug-resistant tuberculosis (MDRTB) can spread very rapidly among HIV-infected persons.²⁹⁻³² In both developed and developing countries, outbreaks of MDRTB have spread rapidly on hospital wards for HIV-infected persons.

Fortunately, DOTS is as effective among HIV-infected TB patients as among those who are HIV negative. Even among HIV-infected TB patients, DOTS cures patients and results in longer, healthier lives.

Tanzania, Malawi, and Botswana have had programmes of directly observed treatment for more than 10 years. Despite high rates of HIV infection, which is present in one third of tuberculosis patients or more, rates of relapse and drug resistance remain low.^{33,34}

Multidrug-Resistant Tuberculosis (MDRTB)

Multidrug-resistant tuberculosis refers to strains of tuberculosis bacteria that have developed resistance to the two most effective anti-tuberculosis drugs available — isoniazid and rifampicin. MDRTB is an emerging and ominous problem worldwide. Patients who do not have MDRTB can

A low cure rate among new smear positive cases will create drug resistant cases faster than these cases can be cured, even if unlimited resources are available easily be cured with 6-9 months of treatment. In contrast, treatment of MDRTB requires at least 18-24 months of arduous treatment with expensive, often toxic, medications. In the United States, treatment of a single case of MDRTB can cost more than US\$250,000. And, the treatment often fails. In a country like India, MDRTB is almost the equivalent of a death sentence, as very few patients have the financial capacity or the stamina to complete the long treatment regimen required.

resistance.^{33,34} If patients are prescribed appropriate treatment and complete that treatment, development of drug resistance is extremely rare. In contrast, when prescribing practices or case holding – or both – are inadequate, drug resistance can emerge.³⁵ Ensuring the cure of new smear-positive patients is the best way to prevent the development of drug resistant tuberculosis and should be the highest public health priority. A low cure rate among new smear positive cases will create drug resistant cases faster than these cases can be cured, even if unlimited resources are available.

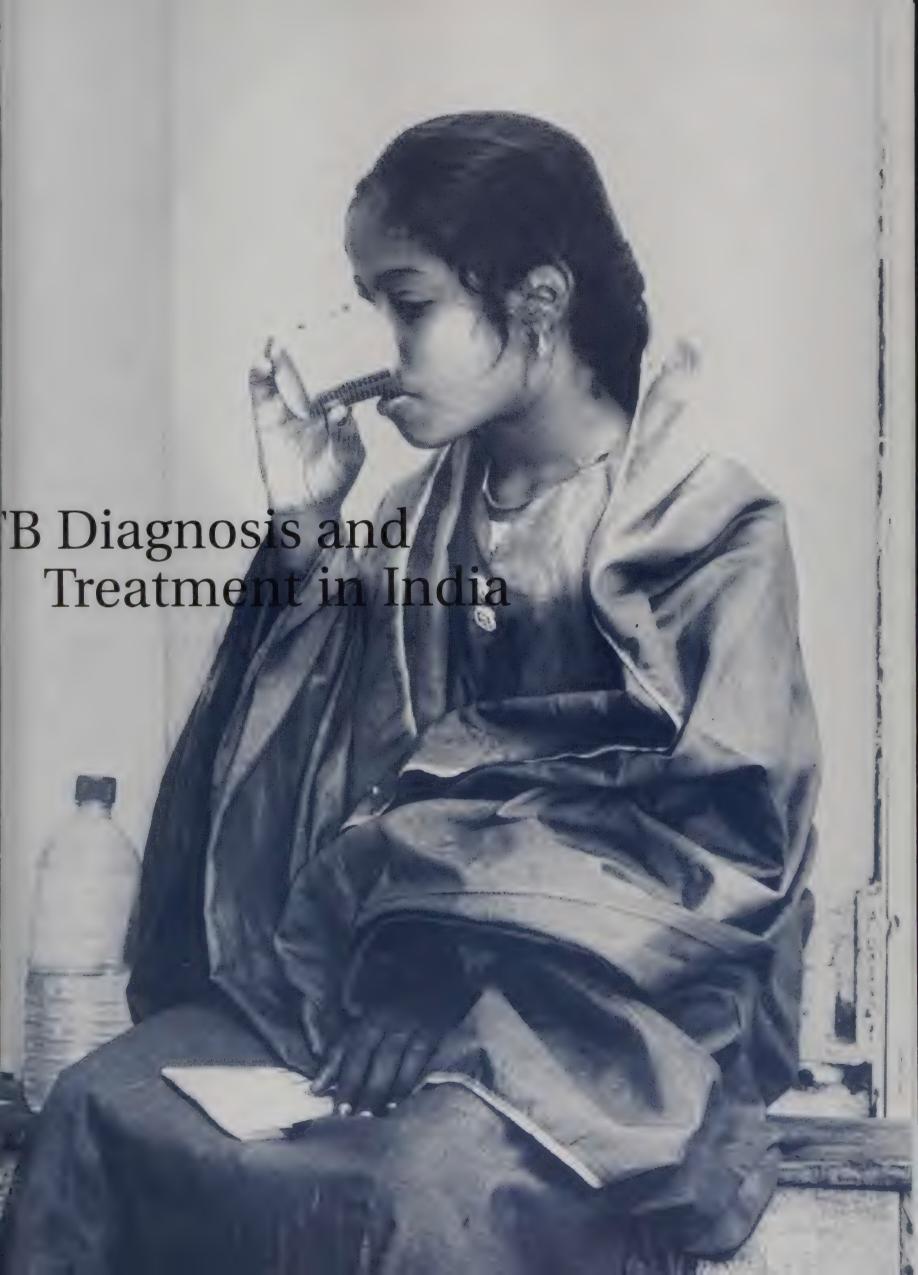
Many of the factors contributing to the development of drug resistance – poor patient compliance, ineffective drug regimens, inadequate follow-up, and poor patient monitoring – flourish in a developing country. DOTS has been proven to prevent the emergence of MDRTB, and also to reverse it where it has emerged.³⁶ The only way to confront the challenge of MDRTB is to improve the treatment programme and implement DOTS as rapidly as possible.

Tuberculosis does not merely reflect socio-economic status – tuberculosis perpetuates and exacerbates poverty

Key Findings and Implications for Action

Tuberculosis is the leading single infectious cause of death in India. In addition to the negative health impact of tuberculosis, it is a substantial economic burden for families and communities. The problems of HIV and multidrug-resistance will make the tuberculosis epidemic much worse unless urgent action is taken. But there is hope – tuberculosis can be cured and the battle against the disease can be won.

- Policy-makers, programme managers, and doctors in public and private sectors should spread the message that TB can be cured and the epidemic controlled. For too long, tuberculosis has been seen as a natural calamity about which nothing can be done.
- Researchers and programme managers should promote much more widespread awareness of the massive health, economic, and social costs of tuberculosis – costs which could be greatly reduced by an effective programme.
- Policy-makers should take into account the negative impact of TB on the
 economy of individual families and of the country. Tuberculosis does not
 merely reflect socio-economic status tuberculosis perpetuates and
 exacerbates poverty. Adequate funding for tuberculosis control is required
 at all levels.
- Policy-makers and programme managers should recognize the serious risk that HIV infection and multidrug-resistant tuberculosis can convert an already-serious situation into a massive and potentially uncontrollable epidemic. It is essential that DOTS is rapidly and effectively implemented before multidrug-resistant tuberculosis and HIV become more widespread. However, implementation must be phased in order to ensure good quality.



In the past, treatment of tuberculosis focused on diet, hygiene, rest at high altitude, and avoidance of fatigue. In the early part of this century, most attempts to combat tuberculosis were led by privately funded voluntary organizations that helped establish tuberculosis sanatoria in the temperate hill stations and offered patient education and even financial assistance to TB sufferers.

After independence in 1947, India began to shape its own health programmes, and two pioneering institutions — the Tuberculosis Chemotherapy Centre in Madras and the National Tuberculosis Institute in Bangalore — were established under the sponsorship of the Indian Council of Medical Research (ICMR) and the Government of India, respectively. These two institutions have contributed world-class research that not only shaped India's subsequent tuberculosis policies but also contributed to tuberculosis control the world over.

The National Tuberculosis Programme (NTP)

India's National Tuberculosis Programme (NTP) was established in 1962 and provided a system – 446 District TB Centres, 330 TB clinics, and more than 47,000 hospital beds – for TB control throughout the country. After more than three decades of operation, the NTP can justly claim to have established an infrastructure for tuberculosis treatment in India. However, with a treatment completion rate of only 30 percent, the programme did not make a significant dent in the problem.

Part of the difficulty undoubtedly lies in the perceived priority of tuberculosis in India. One study of the problem from the Indian Institute of Management, Ahmedabad found that tuberculosis had a low priority compared to other diseases; funding was disproportionately low; senior



programme leaders did not remain in place for long; health staff were pressured by non-TB activities; patients experienced indifferent programme delivery; and the visibility of TB in the media was low.37

Until recently, tuberculosis has had a smaller central budget than malaria, leprosy, blindness, or AIDS. Only guinea worm, among the priority communicable diseases, received less. Negative expectations about the TB programme have tended to become self-fulfilling.

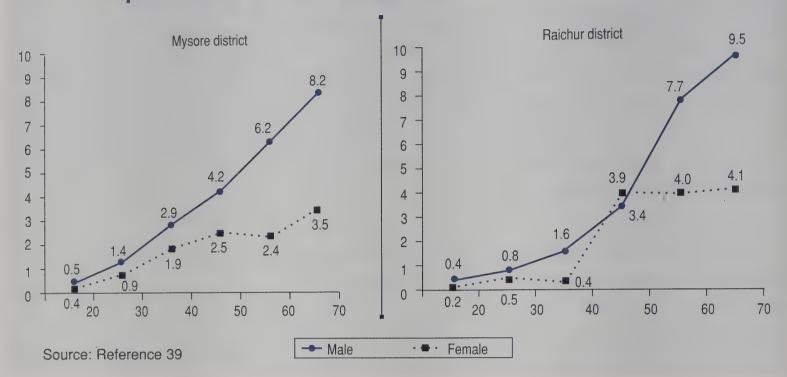
In 1992, a review of the National Tuberculosis Programme by national and international experts - in coordination with the World Health Organization and the Swedish International Development Association – determined that the programme had not had the desired impact on tuberculosis in India.38 The review noted inadequate budgets, a lack of coverage in some parts of the country, shortages of essential drugs, poor administration, varying standards of care at the district centres, unmotivated and unevenly trained staff, lack of equipment, poor quality of sputum microscopy, and focus on case detection without an accompanying emphasis on treatment outcomes. There was a general consensus that, in a revised tuberculosis control programme, the patient would have to be both the starting point and the focus. It is therefore essential to understand the patterns of diagnosis and treatment from the patient's perspective.

"Health-Seeking Behaviour of Chest Symptomatics"

In India, the vast majority of patients with active tuberculosis seek treatment for their disease, and do so promptly. However, many patients spend a great deal of time and money "shopping for health" before they begin treatment, and, all too often, they do not receive either accurate

Virtually all delay in diagnosis is on the part of the health system, not patients

Percent of adults with report of cough for three weeks or more in previous 6 months, by age and sex, Karnataka, 1997



diagnosis or effective treatment, despite spending considerable resources. In a community-based systematic survey in Karnataka, cough for three weeks or more was present in 1.4% of people; rates increased with age, and were higher among males than among females (see figure). Patients usually visit a number of health providers – from general practitioners and general hospitals to practitioners of indigenous medicines and even quacks. Unqualified rural practitioners are the first point of contact for many TB patients.

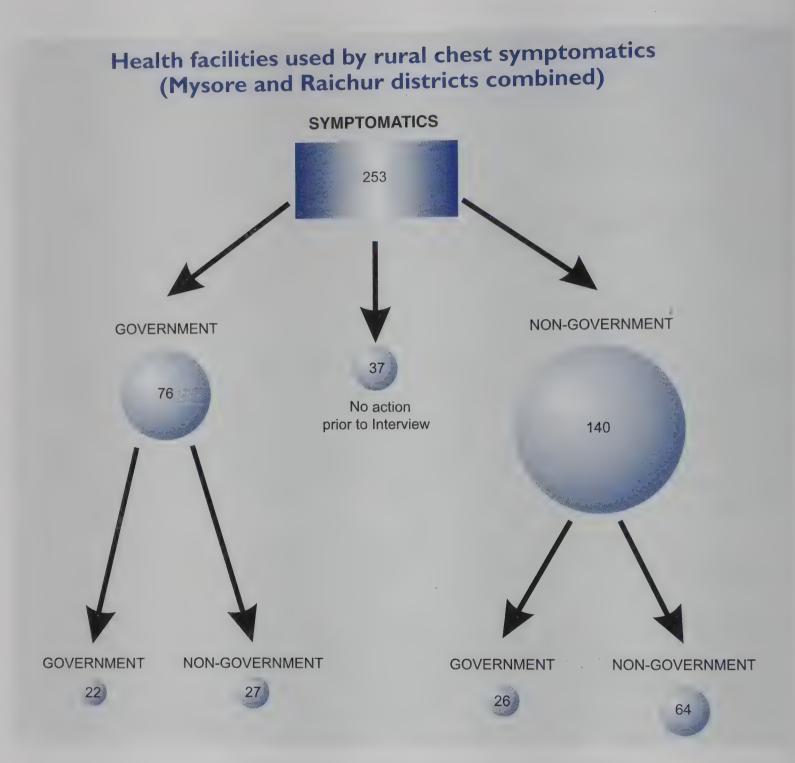
This study also found that patients almost always seek care promptly. The average time it takes for a patient to visit a health facility after the appearance of symptoms was less than 2 weeks. Virtually all symptomatic patients who sought care did so within one month of the onset of symptoms. In areas with better performing health systems, patients sought care even more promptly. The only sub-group which did not seek care promptly was elderly, non-literate males.

Delay between the onset of symptoms and the start of effective treatment is important in the control of tuberculosis because during this time patients are most infectious. Most delay in diagnosis is on the part of the health system, not patients.

One barrier to treatment is the stigma that is still associated with tuberculosis. In many parts of India, this remains a serious problem.

In one recent study, researchers interviewed several hundred patients and their families and found that most patients felt uncomfortable talking about tuberculosis. Several patients denied that they were suffering from the disease or taking treatment for it, and some even refused to mention tuberculosis by name. Patients frequently attempted to hide their disease from their family and community by registering under false names at tuberculosis clinics or by denying their identity when confronted by interviewers.

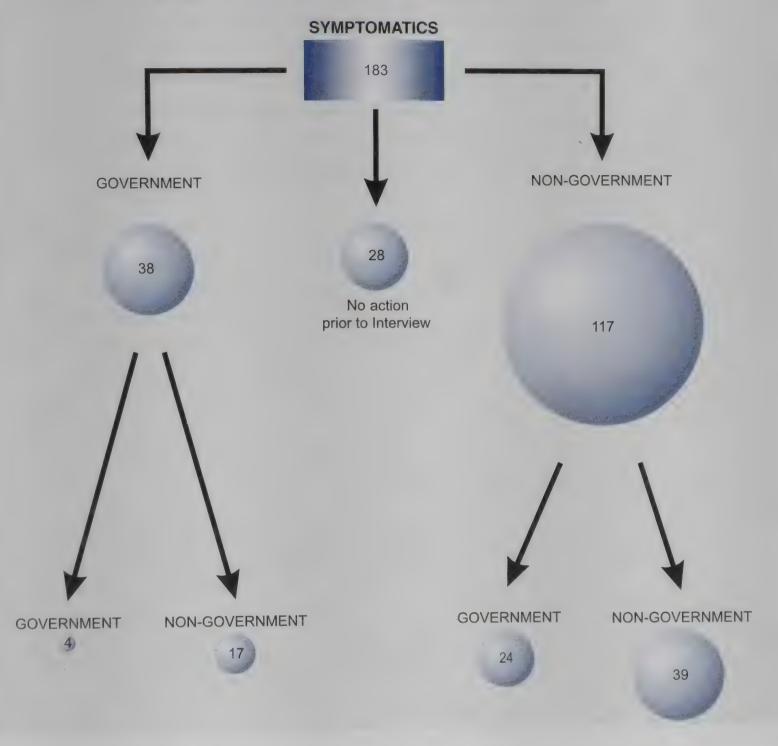
First action taken by chest symptomatics									
	Mysore district		Raichur district		Tamil Nadu		Delhi	Average	
	Rural	Urban	Rural	Urban	Rural	Urban			
	%	%	%	%	%	%	%	%	
Private provider	48	76	93	74	48	57	55	64	
Government facility	51	22	5	25	46	32	21	29	
Self-medication	anness steems	egymph limmin	samples solution	allillado Figurano	4	8	10	3	
Home remedies	April and the second	andonedir			1	2	6	1	
Other	1	2	. 2	1	[1	. 1	8	2	
Total taking action	83	85	90	85	63	80	82	81	
No action prior to			·		0.7	0.0	4.0	10	
to interview	17	15	10	15	37	20	18	19	



Similarly, a study by the Indian Institute of Management³⁸ found that most patients were reluctant to admit that they had TB because they feared stigma, and they preferred not to discuss the disease in the presence of family or neighbours. This was more so in urban than in rural areas. Family support for treatment was more frequent among cured patients than among those who had defaulted.

The majority of TB patients in India who seek help first consult one of India's 10 million private medical practitioners (See tables on pages 25 and 28). In studies that assessed the health-

Health facilities used by urban chest symptomatics (Mysore and Raichur districts combined)



seeking behaviour of chest symptomatics in rural Karnataka and Tamil Nadu, and in urban Karnataka, Tamil Nadu and Delhi, researchers found that 64 percent first sought help from a private provider. Only 29 percent went to a government facility on the first visit. Ramana et al. found that 80 percent of all private practitioners in their study areas in rural and urban Andhra Pradesh were treating tuberculosis. 19

The major causes patients gave for seeking private providers were proximity and convenient working hours, while the main reason for going to government facilities was free treatment (See figures on pages 26 and 27).

Studies have shown that, despite having limited resources, most patients are not promptly diagnosed and treated, and therefore go from one doctor to the next before a diagnosis is firmly established and treatment begins.⁴⁰

In one study, the average number of health providers visited by patients from the time they developed symptoms to the time they registered at a TB clinic was 2.5 for urban patients and 4.0 for rural patients. Not only did this increase the cost of treatment, increasing debt, but it also delayed prompt initiation of treatment, thus allowing disease to spread further in the community.

The total cost incurred by patients shopping for care was about Rs 1000 (\$30) in urban and Rs 630 (\$18) in rural

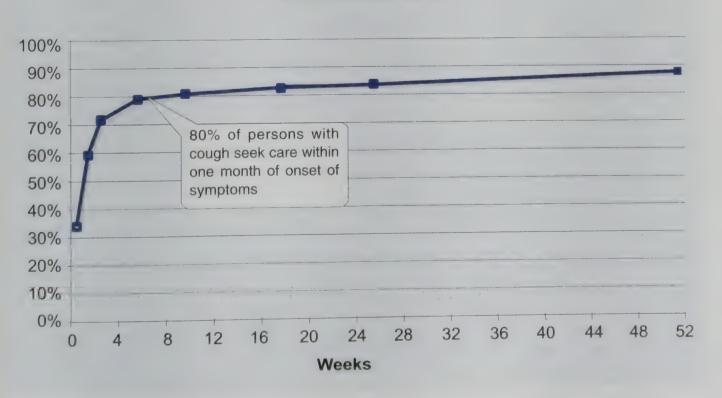
Provider consulted first by patients with tuberculosis							
Provider Consulted First	Medak (rural) %	Hyderabad (urban) %					
Unqualified neighborhood doctor [34] [36] [36] [36] [37] [37] [37] [37] [37] [37] [37] [37							
Qualified neighborhood doctor	25.7	55.2					
Neighborhood doctor (not aware of qualifications) 41.5 41.5 20.9							
Specialist in TB/Chest Diseases	0	.7					
Specialty Hospital	8.6 Herida						
Clinic/Dispensary/PHC	4.3	3					
Hospital Parameter in the Additional Action	(growt) (k. 1.4 - 1.4 (k. 1866)	14.9					
TB Clinic/Hospital	11.4	3.8					

Source: Mapping of TB Treatment Providers at Selected Sites in Andhra Pradesh State, India¹⁹

Karnataka, and about Rs 550 (\$16) and Rs 400 (\$11) in urban and rural Tamil Nadu.

All too often, health providers fail to diagnose the disease correctly, thereby delaying the start of treatment and perpetuating the chain of infection in the community. Many providers do not confirm their diagnosis of pulmonary tuberculosis by sputum examination, relying instead on chest radiographs and thus often incorrectly diagnosing patients to have tuberculosis. In one study in Bombay, only 39 percent of doctors used sputum examination to confirm the diagnosis of tuberculosis.41 Studies in Delhi, Karnataka, and Tamil Nadu revealed that, even after multiple visits, less than one third of patients underwent sputum smear examination. In one study, even after 8 encounters with the health system, less than one third of patients had undergone even a single sputum examination, despite spending 1-6 months of their income. In rural areas, lack of access to effective diagnosis and treatment was even more pronounced (see figure).

Time between onset of cough and first medical visit, Karnataka, 1997



Even when tuberculosis is diagnosed by private practitioners, prescribing practices vary widely. A study of 100 private doctors in Bombay, found that there were 80 different regimens, most of which were either inappropriate or expensive, or both.⁴¹ In a similar survey in Pune, 113 doctors prescribed 90 different regimens.⁴² Private doctors seldom felt that it was their duty to educate the patients about TB and never made attempts to contact or trace patients who had interrupted treatment.⁴³ Virtually no individual patient records are maintained by private physicians.

Despite 8 encounters
with the health system
and the expenditure of
1-6 months' wages, less
than one third of
patients with symptoms
of TB had undergone
even a single sputum
examination for AFB!

Even when patients are eventually diagnosed and then prescribed the correct treatment regimen, many discontinue it if they are not supported and monitored throughout the treatment period. The two main reasons offered by the majority of those who stopped treatment were that they felt better and had therefore discontinued their drugs, and that there was too much cost and trouble associated with getting an uninterrupted supply of drugs.

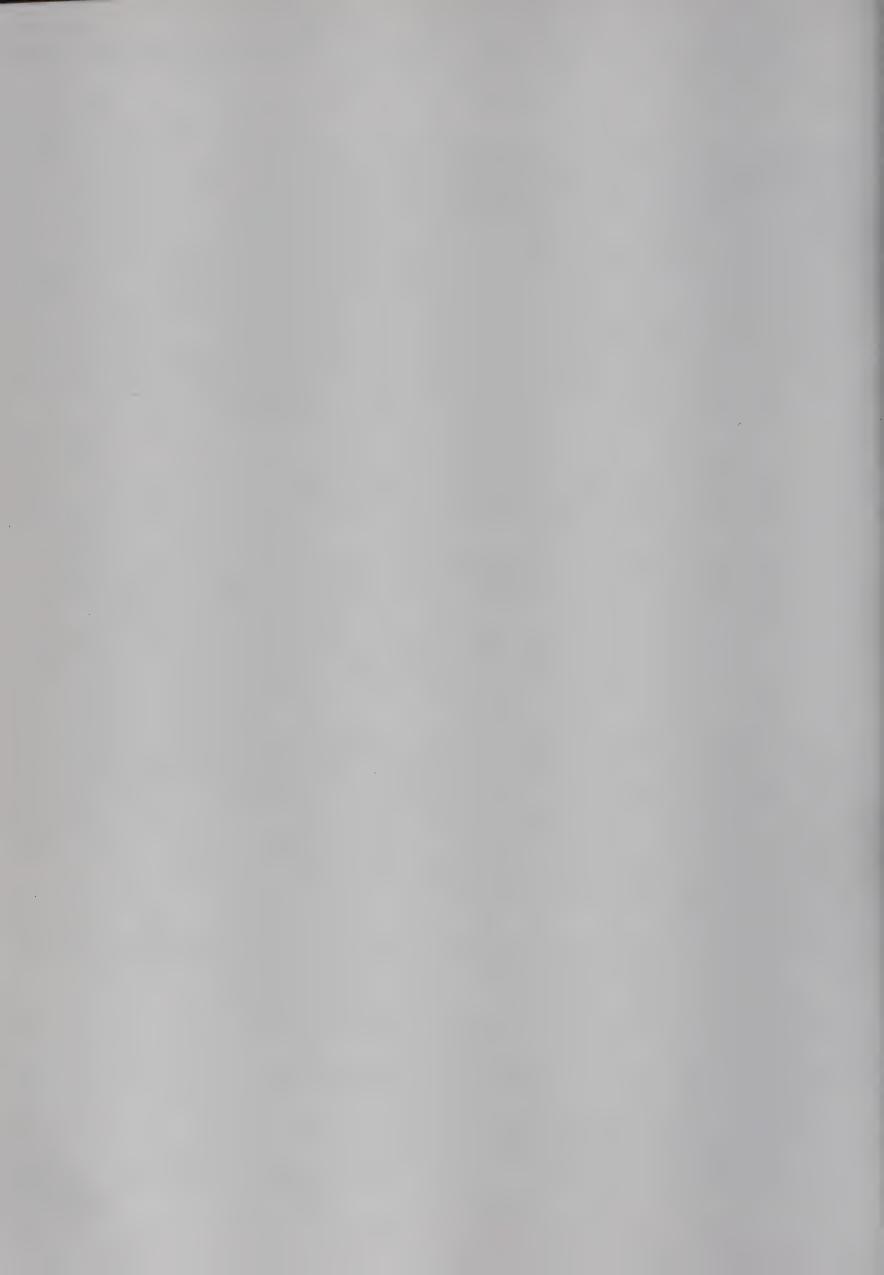
Estimates in India indicate that, of every 100 infectious tuberculosis cases in the community, about 30 are identified in the public sector, of which at most 10 are cured; similarly, about 30 are identified in the private sector, of which at most 10 are cured. Hence, not more than 20 percent of patients who develop tuberculosis in India each year are cured. Many of the remaining patients remain chronically ill or die slowly from the disease, infecting others with strains of the disease which may have developed drug resistance.

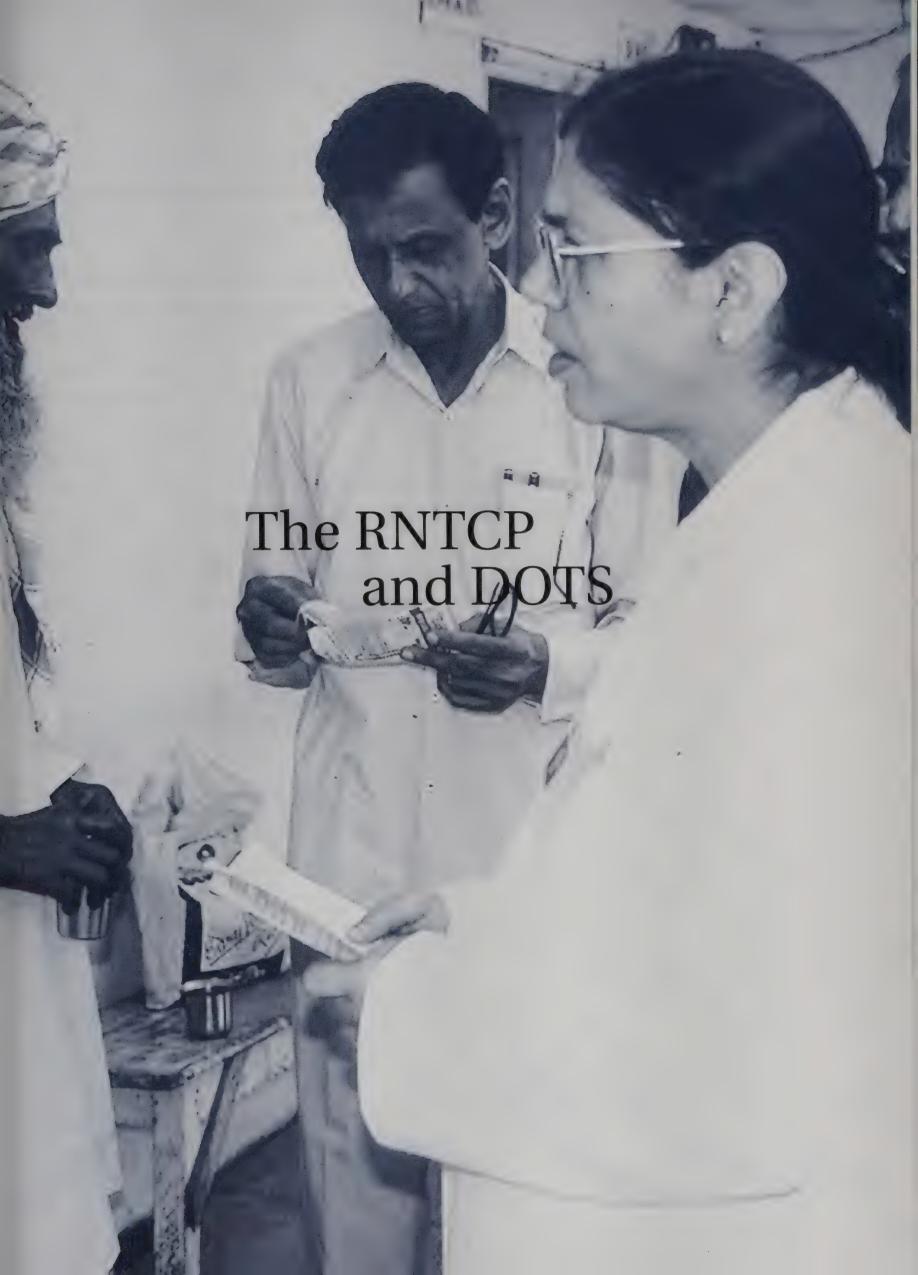
Despite these serious shortcomings, there are signs of hope. Most practicing physicians reported that they would be interested in receiving training on DOTS, and most were willing to have their offices used as centres for treatment observation for their patients, free of charge.

Key Findings and Implications for Action

Patients with symptoms of TB seek care promptly – but in both the public and the private systems, they are neither reliably diagnosed nor effectively treated. Where services are better, people use them more promptly and more often. Despite 8 encounters with the health system and the expenditure of 1-6 months' wages, less than one third of patients with symptoms of TB had undergone even a single sputum examination for AFB! In both public and private sectors, successful treatment of tuberculosis is the exception rather than the norm.

- The behaviour of patients does not need to be changed the health system's response to this behaviour must improve.
- Diagnostic practices need to be strengthened urgently. In both public and private primary health care systems, health workers need to "Think TB" and ensure that all adult patients are asked whether or not they have cough for 3 weeks, and, if they do, that they undergo 3 sputum examinations in a good quality laboratory.
- Programme managers need to publicize the location and availability of free sputum microscopy centres, and the fact that 3 sputum samples should be examined if patients have cough for 3 weeks or more.
- Programme managers need to involve both qualified and unqualified practitioners to refer patients for diagnosis.
- Practicing physicians should ensure that every patient with symptoms of TB undergoes 3 sputum examinations in a quality-controlled laboratory, preferably by referring such patients to an RNTCP microscopy centre.
- In both public and private sectors, improved interpersonal communication, standardized treatment, direct observation at a time and place convenient to patients, and systematic monitoring and accountability are needed urgently.





For the first time since the discovery of effective antituberculosis drugs in 1944, there is a chance of stopping TB, even in a country as vast and varied as India.

Modern treatment can cure virtually all tuberculosis patients. However, it is essential that patients take treatment for the prescribed duration, which in every case is a minimum of six months. Because treatment is of such a long duration and patients usually feel better after just one or two months—and because many TB patients face other problems such as unemployment or poverty—treatment is often interrupted. Therefore, just providing anti-TB medication is not sufficient to ensure that patients are cured.

In 1992, a review committee highlighted the reasons for the failure of India's National Tuberculosis Programme and suggested a revised strategy to combat the disease.³⁸ The recommendations were to:

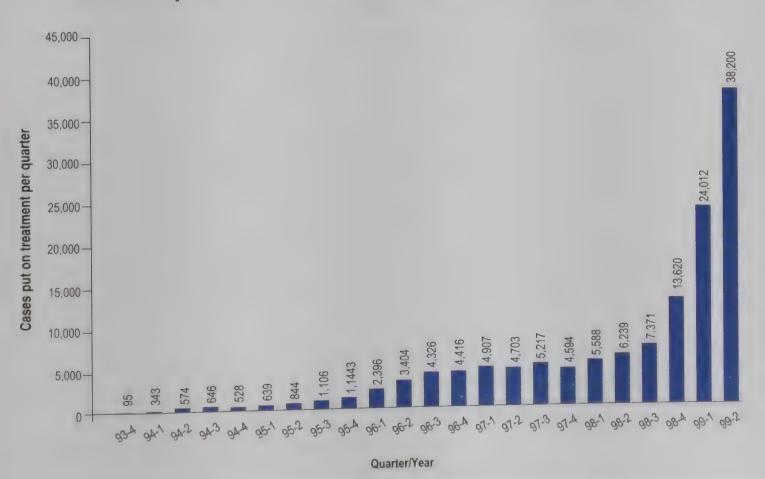
- Strengthen sputum microscopy facilities and ensure good equipment, well-trained laboratory technicians in peripheral centres and quality control;
- Ensure an uninterrupted supply of drugs, even in remote districts;



- Give the highest priority to treating smear-positive patients with short-course chemotherapy under direct supervision (DOTS), involving grass-roots health workers and volunteers as treatment observers;
- Improve training of all personnel;
- Involve NGOs and private medical practitioners,
 because of the large number of patients who by passed the NTP by directly consulting private practitioners;
- Strengthen recording and reporting in order to ensure accountability and emphasis on monitoring of treatment outcomes;
- Encourage operational research that would enhance the efficiency of the programme.

In 1993, this strategy, known as the Revised National Tuberculosis Control Programme (RNTCP), was pilot tested

Patients put on treatment per quarter, RNTCP, 1993-1999





Cured TB patient, Orissa, India

in a population of 2.35 million and later extended to cover 13.85 million in 13 states. In each of these areas, diagnostic practices improved and cure rates more than doubled. Because of these encouraging results, the government decided to expand coverage. A soft loan of US\$142.4 million was successfully negotiated with World Bank, and the RNTCP was formally launched in India on March 26, 1997 with a plan for phased coverage of 102 districts having a population of 271.2 million. The goal of the RNTCP is to cure at least 85% of new sputum positive patients and detect at least 70 percent of such cases. By early 1999, India had the second largest DOTS programme in the world, and more than 150,000 patients had been treated (see figure page 35).

The RNTCP is an application of the principles of DOTS — Directly Observed Treatment, Short-course — to the Indian context. By shifting the responsibility for cure from the patient to the health system, DOTS has proven to be the only strategy that can control TB on a mass basis. Today, the DOTS programme — individual components of which were discovered in India decades ago — is practiced in more than I 10 countries.

Since 1993, India's Revised National Tuberculosis Control Programme has successfully implemented the DOTS strategy in pilot projects with a population of more than 20 million in 13 states throughout the country. In the initial areas of implementation, cure rates of 80 percent have been obtained, with some areas consistently achieving cure rates above 90 percent. In addition, DOTS has been shown to be highly cost-effective. 44,45

More than 40,000 lives have already been saved by the RNTCP. In late 1998 and early 1999, the RNTCP began rapid expansion, with nearly as many patients treated in the first six months of 1999 as in the previous 5 years.

Current Accomplishments of India's RNTCP

- Expansion to cover a population of 130 million in 16 states by 1999.
- Good quality of diagnosis. Half of patients have had laboratory confirmation of their disease (positive smears), compared with 1 in 4 in the previous programme.
- More than 250,000 patients treated by mid-2000.
- Good quality of treatment. In the RNTCP, 8 out of 10 patients have been successfully treated, compared with fewer than 4 out of 10 in the previous programme.
- By curing patients and stopping tuberculosis at the source, the RNTCP prevented more than 500,000 tuberculosis infections by mid-2000.
- By late 1999, more than 2,500 lives were being saved every month –
 patients who would die if the RNTCP did not treat them. In the RNTCP,
 less than 4 percent of patients die, compared with more than 20 percent
 of patients in the previous programme.
- Rigorous training of more than 50,000 health staff, including training of more than 2,000 microscopists and more than 8,000 medical officers.
- Regular supply of good quality drugs and state-of-the-art binocular microscopes.

The Government of India has significantly increased the national budget for TB control, and will increase the coverage of the RNTCP in a phased manner. "The challenge," says Dr Uton Muchtar Rafei,WHO Regional Director for South-East Asia, "is to balance the urgent need to accelerate DOTS expansion with the equally important need for caution so that the high quality of the programme is maintained."

The experience in India, which matches that of many countries, is that phased expansion is critical. Trying to expand too fast can result in a poor programme that can actually worsen the prospects for TB control by increasing drug resistance.

implementation of

DOTS can save literally
millions of lives in
India. Every patient
who is cured stops
spreading TB

At the same time RNTCP is being implemented, the rest of India is preparing for future RNTCP implementation by receiving updated technical material, diagnostic equipment, and an uninterrupted supply of drugs, and by implementing the RNTCP registration system.

The programme is supported by funds from the Government of India – which supports 100 percent of the needs for anti-TB drugs as a centrally sponsored programme – and a soft loan of US\$142 million from the World Bank, as well as bilateral assistance from the British Department for International Development (DFID) and Danida, the Danish aid agency.

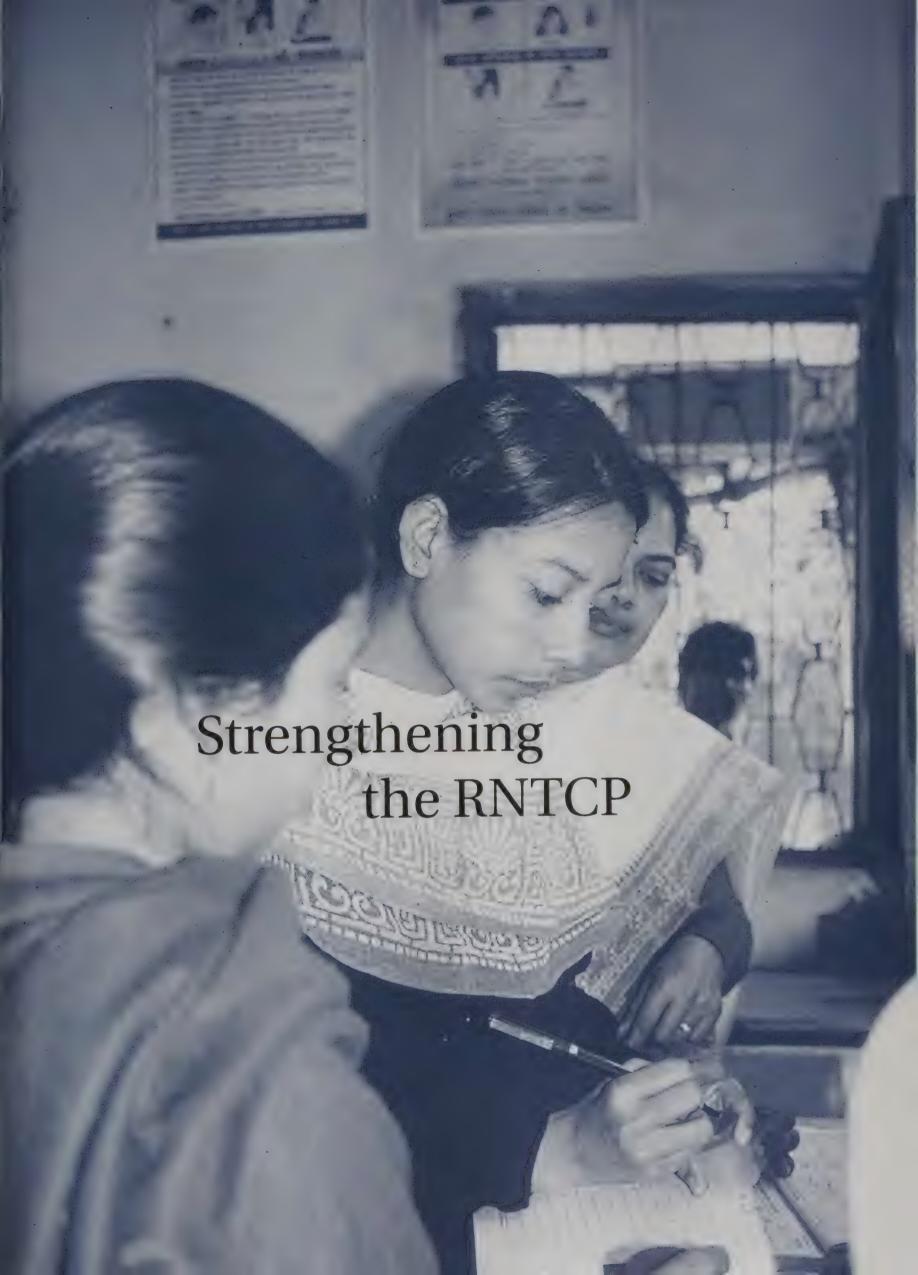
Effective implementation of DOTS can save literally millions of lives in India. Every patient who is cured stops spreading TB. Each life saved represents a child, mother, or father who will go on to live a longer, productive, TB-free, life.

Key Findings and Implications for Action

Forty years after the discovery of the principles of DOTS in India, DOTS is being applied on a mass basis in the country. India now has the second largest DOTS programme in the world. Maintaining the momentum in order to achieve national coverage in a phased manner, and maintaining the quality of services, will require constructive commitment from all sectors.

- In areas where RNTCP is in operation, the availability and success of services should be widely publicized.
- Continued expansion needs to occur rapidly, but only when quality of services can be ensured. A poorly implemented programme is worse than no programme at all.
- Continued intensive supervision and monitoring is required, particularly
 in districts which are just beginning to implement DOTS or which are not
 yet functioning effectively.
- At all levels, the positive achievements and successes of the programme should be emphasized – India is showing the world and its own citizens that it can reliably diagnose and treat tuberculosis in the community on a mass basis.





Some say that, while DOTS may have been successful in Tanzania, China, and New York, it will prove far more difficult in a country as vast and varied as India, with its own unique social and cultural tapestry.

One thing is clear. For the India's Revised National Tuberculosis Control Programme to have the maximum impact, there must be a shared commitment from outside the government, particularly from private practitioners and non-governmental organizations. The government cannot implement the RNTCP alone. In addition, there must be a strong research base and adequate funding at local and regional levels.

"There are 302 private practitioners in our project area. I have contacted every one of them and told them that any patient having a cough of more than three weeks' duration may have TB and should be sent to Mahavir Hospital for free diagnosis and treatment"

Involvement of the Private Sector

The private health sector is the first point of contact for most TB patients in India. Many TB patients in India first seek help from one of India's 10 million private practitioners. Many of these patients spend four weeks or more "shopping for a cure" before they are diagnosed and treated. For patients who remain with private providers, TB cure rates are disappointingly low.

If India is to implement the RNTCP effectively and reach at least 7 of every 10 new infectious cases, involvement of the private sector is essential. The introduction of the Revised National Tuberculosis Control Programme (RNTCP) offers a unique opportunity for collaboration between public and private sectors.

Mahavir Trust Hospital – A New Approach to DOTS Through a Public-Private Mix

A Case Study

In a joint effort with the government and the private sector, the Mahavir Trust Hospital, a nonprofit specialty hospital in the

city of Hyderabad, Andhra Pradesh, has undertaken a project that involves individual private practitioners in the DOTS programme.

"The RNTCP started in the City of Hyderabad in 1995," says Dr. K.J.R. Murthy, a senior chest specialist in Hyderabad who is the Medical Advisor of the Mahavir project. "Dr. Kumar Rao, then director of the state TB centre, asked me to be one of the facilitators, and, when the government was about to launch the programme, I requested that they give one of the TB facilities to Mahavir Hospital on a trial basis. Until then, the entire programme was being carried out by the government, and there was opposition to giving any part of it to private hospitals. But I pointed out to them that 80 percent of TB patients were first seeking treatment in the private sector. And private facilities were not following the current guidelines for either the diagnostic approach or the treatment regimens. Patients weren't diagnosed in a timely manner, and they didn't get the right treatment or the proper duration of treatment. That is costly, both in terms of lives and money.

"If there could be an intervention at the primary level,

sensitizing these private practitioners to refer their chest symptomatics to a facility where investigation and treatment is done free of charge, it could make a big difference. So the state TB director gave us this project."

Mahavir's project area now covers a population of 500,000 in Hyderabad, a city of more than 5 million. About



75 percent of the people in Mahavir's project area are slum dwellers, who are at a higher risk of TB.

The British Department for International Development (DFID) provided funding for the Mahavir project via the World Health Organization, which provided technical support. The Central and State governments provided training, policy direction, drugs, and other support.

As soon as the project was approved, Dr. Murthy and his colleagues began a campaign to educate local physicians about DOTS and create a mechanism for referral of TB patients, with the assurance that the private physician would continue to be the patients' primary caregiver.

"There are 302 private practitioners in our project area," says Dr. Akbar Yazdani, Medical Officer of the Mahavir project. "I have contacted every one of them and told them that any patient having a cough of more than three weeks' duration may have TB and should be sent to Mahavir Hospital for free diagnosis and treatment."

"These meetings have provided an opportunity to freely exchange ideas and address the concerns of the private practitioners, especially regarding the likelihood of losing their clients. A referral card was specially developed for this.



"We made it absolutely clear at the very outset that these patients will continue to be in their charge for any problem other than tuberculosis. Mahavir will only provide treatment for TB. For any problems other than TB, the patient has to see their private practitioner. If any patient complains of any other condition, we politely tell them to go to their doctor. So the private practitioner is not losing clientele."

"This arrangement has worked out very well for us and for the doctors. Most doctors see this as an opportunity to broaden their patient base. No doctor that we have dealt with feels that he is losing patients when they come here. That's the big plus. Their clientele has actually increased because of the early diagnosis and quick treatment of their patients. They are part of the national health programme, which is a good advertisement for their services."

"Since we started in September 1995, our patient referrals have doubled every quarter. We are making the diagnosis earlier, which is very important with TB."

Initial diagnosis and treatment of suspected TB patients is done at Mahavir Hospital. Once the diagnosis is confirmed, a detailed counseling session is held with the patient, who then comes into Mahavir for treatment three times in the first week.

"Every time patients come for treatment, they are told about the nature of the disease, that all treatment and all medications are free, and the necessity of continuing their treatment," says Dr.Akbar. "Patient education is a very important part of what we do." The fact that medicines are completely free, and that patients may, if they wish, continue to receive directly observed treatment at Mahavir Hospital, is emphasized. Patients receive their first week (three doses) of medicine at Mahavir, during which time the patient's name is writen on the box containing the entire course of the medicine and fact that the treatment is free is emphasized.

In addition to the TB clinic at Mahavir Hospital, the project opened 26 neighborhood DOTS centres so patients can receive treatment within easy walking distance of where they live. The clinics open at 7:30 am so patients can take their medicine and then go to work.

"These private centres already exist. The government doesn't have to spend any extra money for this. All they have to do is utilize their services and ensure that RNTCP policies are followed"

"In our project area, which has a population of more than 500,000, there is only one government clinic," says Dr. Murthy. "That clinic is about six to eight kilometers from the farthest point, so patients have to spend a lot of money and time in order to go to the government clinic. Also, the government clinic opens around 9:00 to 9:30, so patients have to miss work in order to go there. They lose wages.

"With our clinics, most of the patients are still going to work, and that is very important. We encourage them to go to work as early as possible, rather than getting laid off and losing their wages. They are coming to a center nearby in their neighbourhood – the farthest a patient has to walk is only about half a kilometer – they take their medicine and then go to work. So this sort of arrangement works out well for the patients. They are not spending time and money on transport."

All patient addresses are physically verified at the start of treatment to reduce the chance of default. If a patients does not come to a clinic for treatment by noon, a paramedic is sent to the patient's home.

"There are almost no defaulters in our programme," says Dr.



TB Clinic, Hyderabad

Akbar. "If patients don't show up, a paramedic goes to their house and brings them back for treatment."

The results of the Mahavir programme from 1995 through 1998 have been outstanding. They have achieved the national goal of 70 percent case finding and a cure rate of more than 85 percent of new smear-positive patients.

Nearly two-thirds of Mahavir's patients have been referred by private physicians.

"The RNTCP requires that cure rates — that is, patients completing their treatment and getting converted from sputum-positive to sputum-negative — must be 85 percent," says Dr. Murthy. "We have been able to achieve 95 percent. We have even been able to achieve an 85 percent cure rate with patients who had defaulted earlier."

Women accounted for nearly half of all smear-positive patients in the Mahavir project, compared with slightly more than one-third in other DOTS areas. This may mean that women have better acceptance of public-private DOTS services than the government programme, says Dr. Murthy.

As with any programme, the project is not without problems. The Mahavir project is located in an area which is virtually devoid of government services, unlike much of India where government services exist but may not be functioning optimally. This makes it an atypical context. How much of the success of the project is a result of the unique contribution of the specific staff is also unclear. Finally, despite the high quality of services offered, private physicians seem to refer only patients who do not have sufficient resources; ironically, better off private patients may receive lower quality diagnosis and treatment as a result.

The question for any successful programme is, 'Is this replicable?' Can the Mahavir programme serve as a model for other parts of India and other countries? Dr. Murthy thinks so.

"The rest of India is basically the same as Hyderabad," he says. "The doctors are there. The patients are there. All that is required is a trust hospital or other institution where there is a person who could act as a leader.

"Our experience is very clear. A strategy of collaboration between the public and private sectors is feasible, and it's cost effective for everybody – patients, doctors, and the government"

"The real question is whether the government dispensaries can do this job. Certainly the government dispensaries are capable. Nobody is questioning their competence. But what is important is the coverage. How much can they cover? With all metropolitan cities expanding, the government cannot keep up by starting new health centres. It's not cost effective.

"The cost of running a government clinic comes to about 40,000 Rupees (US\$1,000) a month. So if one has to have so many government centres, it's going to be very costly. Private centres already exist. The government doesn't have to spend any extra money for this. All they have to do is utilize their services and ensure that RNTCP policies are followed. Patients are going to the private doctors anyway, whether we like it or not.

"Our experience is very clear. A strategy of collaboration between the public and private sectors is feasible, and it's cost effective for everybody – patients, doctors, and the government."

Tuberculosis Research Centre – ACT and Private Practitioners

A case Study

One of the goals of the Tuberculosis Research Centre in Chennai, Tamil Nadu is to establish links that help bring the private and public health sectors together. Recognizing the vital role that private practitioners play in the control of tuberculosis in the community, TRC enlisted the help of *The Hindu*, one of India's largest newspapers, to help promote TB awareness among private practitioners.

After discussing the problem, representatives of *The Hindu* and TRC met key community leaders and doctors to organize a forum for TB advocacy. At this forum, private practitioners

could share their knowledge and experience and learn more about the RNTCP.

"The Hindu got involved because it is very conscious about the role of media in health awarness," says a senior TRC scientist. "Every Sunday they have a prominently placed article about health.

"The idea for the forum came about on World TB Day, March 24, 1998. We held a meeting and explained that the involvement of private practitioners was the biggest problem we faced. This led to the idea for a big open house meeting."

The Hindu agreed to promote the forum, and the publicity they generated drew a great deal of attention, both to the meeting and to the scope of the TB problem in Chennai.

"It generated a lot of curiosity," says a TRC researcher. "We expected that about 100 doctors would come to the forum, but more than 350 showed up.

"The private practitioners realize TB is a real problem, but they are a very independent group and don't like to be regulated. They each have their own beliefs and treatment regimens. They were aware of the government programme, but they weren't following it.

"We told them that this is not a rigid programme and that we wanted to work with them. We stressed two key issues: transparency for the patients and financial benefit for the doctors. Medicines must be free, but participation in DOTS would not interfere with their ability to get paid for their other work. The idea is that they should get involved because it will strengthen their role in the community."

Medicines must be free, but participation in DOTS would not interfere with the doctors' ability to get paid for their other work The doctors were asked to participate in training and follow the guidelines of the RNTCP. Sixty percent said that they would be willing to follow the DOTS programme, and more than 50 signed up for further training and workshops. This has led to the formation of ACT – Advocacy for Control of Tuberculosis – which is a community initiative for TB control in Chennai which is supported by TRC.

Under the aegis of ACT, workshops have been held to familiarize participating physicians with the concepts of diagnosis, treatment and follow up under the DOTS programme. Physicians have also met on several occasions to discuss problems relating to TB control.

Laboratory technicians from 21 private clinics have been trained by the TRC to carry out sputum smear examinations. Their performance is then evaluated by periodic quality control checks. TRC has also trained people such as doctors' receptionists to be DOTS practitioners.

"At first the doctors feared that the record-keeping would be too much work." But TRC provided them with a patient diary and showed them that the DOTS provider — a receptionist or other staff person — could handle that. In the case of defaulters, if the patient doesn't show up for treatment, the responsible TB agency follows up, with the help of ACT social workers.

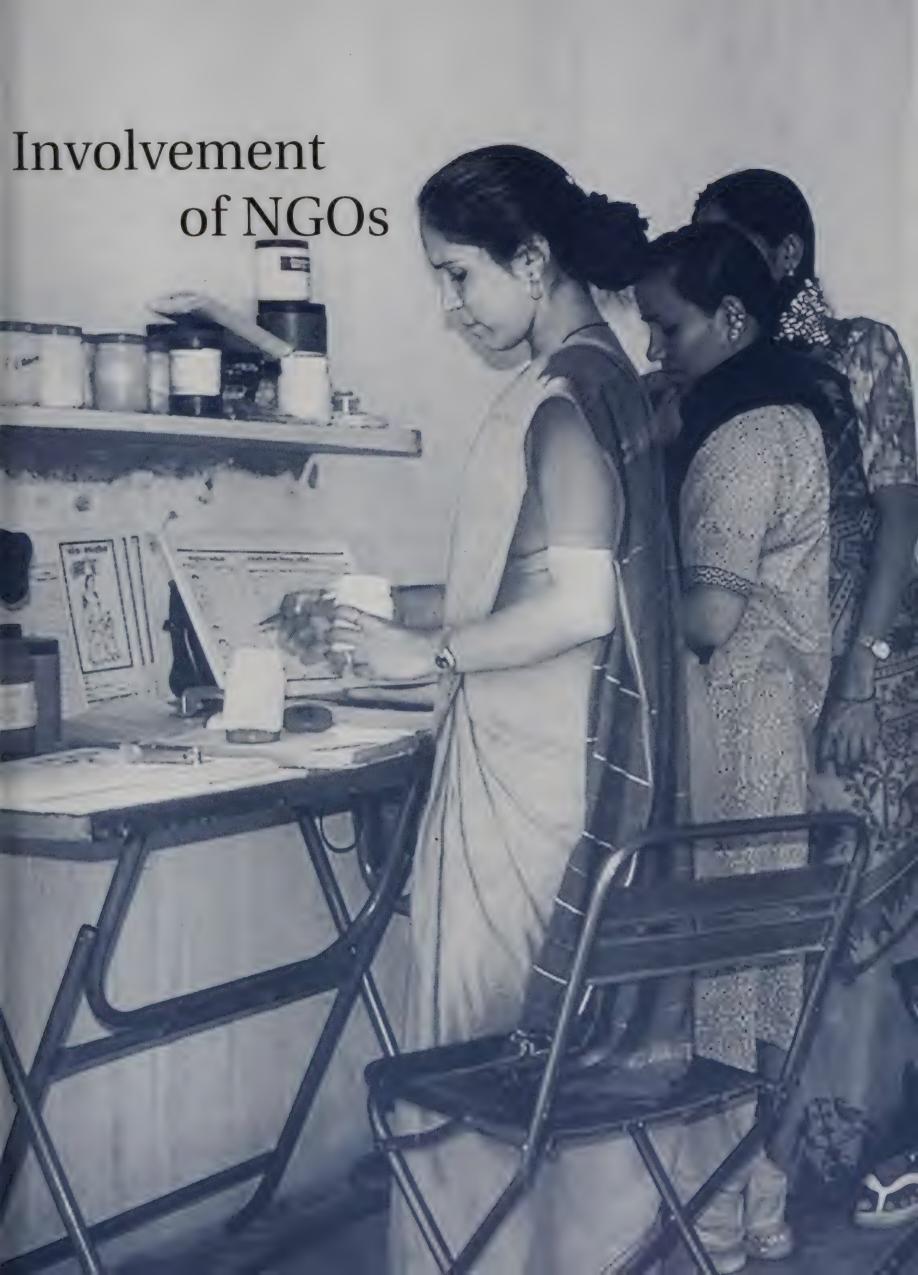
"These private clinics are now providing treatment according to government guidelines. They are doing sputum exams every two months and documenting everything. This is a very promising programme. It marks the beginning of a new phase in the control of tuberculosis which harnesses the potential of the private sector."

Mahavir Hospital Public-Private DOTS Project: Key Lessons

- Successful coordination between public and private sectors can result in more effective service to patients.
- 2. Effective coordination requires clear delineation of responsibility and ongoing and frank communication between public and private sectors.
- 3. Patients must be clearly and repeatedly informed that treatment is free of charge, and must be given the option of receiving treatment observation either through governmental or non-governmental channels.
- The first several doses of anti-tuberculosis medicines should be given at the base institution, where the fact that treatment of tuberculosis is free of charge can be emphasized. The patient should then be given the choice of continuing to receive treatment observation at this location, or at a peripheral, private location.
- 5. During treatment, the patient should be periodically interviewed (for example during submission of follow-up sputum examinations) to determine that treatment is being given as per policy and free of charge.
- 6. Coordination is simplest in areas where the governmental facilities are absent or extremely limited. Where governmental facilities are in place, additional inputs and intensive efforts will be needed to ensure effective cooperation.









SEWA Clinic, Ahmedabad

In order to be fully effective, the RNTCP needs broad participation by community-based, non-governmental organizations as well as private health care providers. Because the treatment regimen under the DOTS strategy has been standardized, implementation of DOTS does not require specialized medical professionals. Local paramedical staff can be trained to supervise DOTS treatment.

Self-Employed Women's Association (SEWA) A Case Study

The Self-Employed Women's Association (SEWA) is an organization of nearly a quarter of a million women workers in the unorganized sector in India. SEWA has members in six states in India, with the largest participation in Gujarat, where it was founded.

Women in the unorganized labor sector – home-based workers, hawkers, vendors, manual laborers and service providers – constitute more than 94 percent of the female workforce in India and the majority of workers in this labor sector. While they contribute significantly to the national economy, workers in the unorganized sector have no job security or social services such as health insurance or child care.

"That means they have no labor union, no day off, no insurance, no social security," says Mirai Chatterjee, General Secretary of SEWA. "They are dependent on their wits for survival."

Because of the lack of available health care and insurance coverage for poor women and their children, SEWA decided early on to develop a community health programme for its members. As SEWA's health care workers began providing

services in villages and urban slums, it soon became apparent that tuberculosis was a major killer of SEWA members and their families.

"If you work among the poor, you can't avoid TB," says Chatterjee. "It is one of the great health scourges of our time. Most of our members live in crowded, unsanitary conditions and often work in hazardous, dust-filled occupations that can lead to lung diseases.



Many work in the tobacco industry, for example, where there is dust everywhere. Others shake the dust out of empty cement bags so they can be washed and reused to pack vegetables. Others sort waste rags and clean them to make quilts. There is a lot of cotton dust generated in this work. This can lead to fibrosis of the lungs which can predispose to TB."

A team of 20 full-time SEWA health organizers now provide a range of 14 primary health care services to members.

Because SEWA's overall approach is holistic, health and economics are linked.

"TB is a great drain on our members' resources," says
Chatterjee. "No sooner do our members get a few extra
rupees into their pockets than they face a health crisis. They
get caught in a cycle where they get a little ahead, but then
either they or a family member gets TB.

"These people only earn about 20 rupees a day, and the drugs for TB cost 45-50 rupees a day. This leads to a downward economic spiral for the family. With TB, you can't do heavy labor, so you can't work, and then you go even further down into the cycle. We call it the work—health cycle. So that's why SEWA has been involved with TB from the very beginning."



To learn how they could more effectively deal with TB, SEWA representatives met with Dr. B.M. Soni, then Assistant Director of the Gujarat State TB Association, in 1993. Dr. Soni described the new TB programme to them and suggested they get involved.

After that meeting, SEWA started a TB awareness programme and began to identify persons with suspected TB among their members and the community and to enroll them in the new programme. SEWA also became a distribution point for TB drugs and provided follow up to make sure that patients were taking their medications.

Early in 1999, SEWA launched a pilot TB project in the northern zone of Ahmedabad.

Working through Lok Swasthaya – a SEWA-sponsored health cooperative of traditional birth attendants and village-level community health workers – neighbourhood DOTS providers disseminate information about TB in the community, identify suspected TB patients and refer them to microscopy centres, provide DOTS treatment, ensure follow-up sputum examination at prescribed intervals, and work closely with TB patients to ensure full treatment. All of this work is supported by, and closely coordinated with, the Ahmedabad Municipal Corporation.

SEWA has also opened TB centers in two Ahmedabad neighbourhoods. One clinic serves about 75,000 working class people – mostly incense rollers and construction workers; the other a densely populated area of vegetable vendors who are relatively "well off," earning 30-50 rupees per day.

"Most of them begin work at 4:00 am, so they don't have much time for TB treatment," says Chatterjeee. "That's why we put in community education from day one. Ex-TB patients go out into the neighbourhood to talk about TB."

One of SEWA's neighbourhood clinics has a qualified laboratory technician on staff, and both are staffed by community health workers. To ensure laboratory quality, sputum slides are also examined by the senior TB lab supervisor and a doctor.

As a token of their confidence in SEWA's programme, Ahmedabad's Chamanpura TB hospital recently handed over the keys to one of their clinical laboratories to SEWA's senior health organizer.

"There were about 300 people at the event," says
Chatterjee, "including officials from the municipality and
many private doctors. It demonstrated their confidence in
our work."

SEWA is maintaining sputum request forms, laboratory registers, treatment cards, the TB Register, and referral forms and reporting formats according to RNTCP standards.

"At the end of this project, we expect to achieve an 85 percent cure rate and identification of at least 70 percent of the new sputum positive cases," says Chatterjee. "We also expect greater awareness of TB in the community. What we ultimately hope to develop is a model for TB control in poor communities which is managed by the local women themselves. If this programme works here, we want to expand to rural areas."

"What we ultimately hope to develop is a model for TB control in poor communities which is managed by the local women themselves"

The Nehru Nagar TB Centre

A Case Study

Founded in 1970, the Nehru Nagar Chest Clinic (NNCC) in the south of Delhi covers a geographical area of about 80 sq. kilometres and serves a population of approximately 1.4 million people, mostly migrants and slum dwellers. Nearly one third of the chest clinic's clients come from outside the service area.

In 1996 the Nehru Nagar Chest Clinic was one of two chest clinics in Delhi designated to expand DOTS treatment under the Revised National Tuberculosis Programme, with support from the British Department for International Development (DFID). By early 1999, more than 4,000 patients had received DOTS at Nehru Nagar, with 8 out of every 10 being cured.

By early 1999, more than 4,000 patients had received DOTS at Nehru Nagar, with 8 out of every 10 being cured

"As the programme has developed over the past two years, we have opened 14 neighbourhood clinics," says Dr. U.C. Dhawan, Medical Superintendent and Chest Specialist at the NNCC. "Each centre serves about 100,000 people, and they are about two kilometers apart. This makes it pretty convenient for patients to get to the centres.

"We have had a very good response so far. As soon as patients know that a centre is there and that TB drugs are available, they start to come. The only problem is with the hours. Patients who have to be at work very early often can't get there. The commonest group of patients who refused or were not enrolled for DOTS had problems with time. This was particularly true for those who were daily wagers or had fixed work timings or school children. We need early morning hours at the clinic.

"We thought about establishing centers in the workplaces, but there is still a stigma attached to TB and

patients are afraid they might lose their jobs, so they won't come."

The Nehru Nagar TB Programme is one of the largest in Delhi. In addition to the 14 neighbourhood centers, there are a number of sub-centers in the programme area that are run in cooperation with non-governmental organizations.

"The RNTCP is only going to work if we involve NGOs and other institutions," says Dr. Dhawan. "Sometimes the NGO approaches us and asks to help, sometimes we approach them. We now have five or six clinics in the Nehru Nagar district run by NGOs. One of these is in a Hindu temple where they have set aside a room for TB treatment. Paramedics collect sputum specimens and supervise treatment. Another clinic brings patients here for examination. Then they take back the medications and give them according to DOTS guidelines. Another clinic sent their lab technician here to Nehru Nagar to be trained. They also get drugs for their patients here."

"The onus of treatment is on the health worker now, not the patient"

Each of the 14 NNCC neighbourhood centres is staffed by one microscopist and one medical worker called a TB Health Visitor. Doctors associated with the Nehru Nagar Chest Clinic make regular visits to the centers to check on medicines, records, and lab procedures.

As occurs in all RNTCP areas, when suspected TB patients come to the center, they produce a spot sputum specimen and are given a container to take home for an early morning specimen. The next day at the center they bring the early morning specimen and give a third sputum specimen. If the lab report shows that the specimens are positive, the patient is examined by a doctor, and a box with the whole course of treatment is provided for that particular patient and stored at the centre.

"Seeing the complete supply of drugs for the entire treatment period in a box labeled with their name gives patients hope and confidence," says Dr. Dhawan.

TB patients come to the centre for observed treatment three times a week for the first two months of the intensive phase, and then once a week for the continuation phase. During the continuation phase, patients are given two doses to take at home. On their weekly visits to the clinic, they bring in a card and the empty blister packs.



The centre verifies patient addresses when they are first enrolled in the programme. If they do not show up for treatment, the health visitor goes to their house. If a patient misses three appointments, the supervisor follows up, and, finally, the doctor.

Before the DOTS programme, less than 40% of patients completed their treatment. Today, the NNCC has achieved a cure rate of more than 80

percent of new sputum positive cases under the RNTCP.

"Before DOTS, we didn't do proper analysis, monitoring, or supervision," says Dr. Dhawan, who has spent more than 20 years treating TB. "There's a vast difference today. The supply of drugs was not consistent then; now we have guaranteed medications. We had only two microscopes then; now we have fourteen. The old programme was restricted to a few clinics; now we have neighbourhood centers. The onus of treatment is on the health worker now, not the patient. When patients are taking the medication in front of us, we are certain that they are actually taking it. The full course of treatment is guaranteed. Also, because it's a short-

course of treatment – six to eight months instead of one to one-and-a-half years – patients are much more likely to stick with it. This programme is much better.

"Before, TB was a part of life," she says. "No one bothered to do much about it. Now everyone is taking an interest in TB. There is a strong will to do something."

Sivananda Rehabilitation Home - Involvement of Leprosy Programmes

A Case Study

The Sivananda Rehabilitation Home was established in Hyderabad in 1958 for the treatment and rehabilitation of destitute leprosy patients. Initially serving about 50 patients, Sivananda has expanded to include a 200-bed referral hospital and housing for 900 patients and their families on its 51-acre campus. Sivananda serves a population of 1.5 million in the Hyderabad area and operates an outreach programme in which a team of more than 20 trained workers conduct house-to-house visits to ensure early detection and prompt treatment of leprosy.

In 1995, Mahavir Hospital asked Sivananda to collaborate in the tuberculosis control project covering a population of 500,000 in Sivananda's catchment area.

"When we started a pilot project to implement the RNTCP in Hyderabad, we did not have enough paramedical workers," says Dr. K.J.R. Murthy, Medical Advisor to the Mahavir TB Control Programme. "Sivananda allowed us to use some of theirs.



When we scaled the programme up to cover a larger population, we continued the same arrangement."

Dr. P. Hrishikesh, Chief Administrator of the Sivananda Rehabilitation Home, notes that the project with Mahavir is a close collaboration in which Sivananda provides community outreach.

"This is about involving the private practitioners in the area to see that they refer patients and to ensure that patients are not lost to treatment," says Dr. Hrishikesh. "Because it is situated in our area, we have the supervisory part of it. We are a partner with Mahavir.

Successful projects do not just happen – they require nurturing, communication, and careful monitoring "We are familiar with the area, the people, and the houses, even down to block by block maps of each dwelling. Since we have been operating in this area for nearly 20 years, we are able to deal with any problems that arise, whether from the patient or the private practitioner."

At the beginning of the project, Sivananda sent some of its staff to Mahavir Hospital for training. They have also allotted two of their workers to Mahavir Hospital for the TB project.

"Now that leprosy is coming down, this is an opportunity for our health care workers, because they have already got the skills and the expertise," says Dr. Hrishikesh. "After a good orientation and training about tuberculosis, they can do a great job and be very well utilized. We already have some health care workers who have been appointed to this project. It is their duty to visit the patients and the private practitioners to ensure that the patients take their drugs. We have already tried it and it has been successful. Our laboratory workers have also been trained in sputum examination, and, eventually, we will take on some of those responsibilities."

Dr. Murthy hopes that there will be an expanded role for Sivananda when the RNTCP expands to cover more of the outlying populations of Hyderabad.

"Another place where NGOs might be helpful is in the rural areas," he says. "We don't have a presence there, and we want someone who has strength there, a base. Sivananda has that for leprosy. So I hope that the same type of public/private mix can be extended to rural areas where leprosy organizations are present."

Key Findings and Implications for Action

Each community has strengths, and these strengths can be enlisted to support effective diagnosis and treatment of tuberculosis patients. But in each community, the strengths are likely to be different. Thus, a general rule is that local conditions need to be analyzed and local arrangements need to be made. However, there may be no general rule about what those conditions are and what the arrangements should be. Just as each individual unique, so is each community. In some, strong non-governmental organizations can play an important role in tuberculosis control. In others, institutions can serve as key intermediaries between the government TB programme and private physicians. NGOs and private physicians are often closer to, and more trusted by, TB patients. These strengths can be harnessed to extend the reach and improve the efficacy of DOTS – but only with careful safeguards to ensure that diagnosis and treatment are given correctly, conveniently, and free of charge. Successful projects do not just happen – they require nurturing, communication, and careful monitoring.

- Policy-makers should provide a broad framework for coordination on DOTS, but allow local flexibility within this framework.
- Local programme managers should analyze and evaluate resources available in their community. The goal is to identify facilities and means by which patients may be diagnosed earlier in the course of their tuberculosis disease, and resources by which patients can be given observed treatment more conveniently.
- Policy-makers, programme managers, and non-governmental organizations should recognize that successful collaboration requires training, ongoing communication, monitoring, and supervision. Expectations on the part of all parties need to be explicitly stated at the outset, and two-way feedback needs to be frequent and frank.
- Non-governmental organizations should assess their strengths and potential contribution to effective diagnosis and treatment of tuberculosis. Those with a strong presence in the community can play an important role in control of the disease.
- Private physicians should coordinate with the governmental TB programme in their area for diagnosis, treatment, and monitoring. No patient should ever be started on anti-TB treatment unless a full course of treatment can be ensured.



DOTS is the best treatment strategy available today, but it does not and cannot remain static. DOTS has evolved through decades of research — much of it done in India — and it must continue to evolve as it adapts to local situations and emerging scientific data.

A good research programme uses scientific data to better define the problems of TB control and to try out interventions to solve those problems. Operational research provides programme managers the tools they need to analyze their programmes and provide continuous quality improvement. The goal is to improve the diagnosis, care, and access for TB patients by translating the results of that research into policy and practice. India's national tuberculosis programme must be supported by research that continuously provides better tools for diagnosis, treatment, and monitoring.

India has been a leader in tuberculosis research, and it is continuing to promote scientific enquiry and investigation as it implements the RNTCP throughout the country. Studies of the burden of tuberculosis infection and the prevalence and the trend in drug resistance are underway. Research institutions have been asked to develop protocols on modalities of involving the private sector, analysis of the strengths and weaknesses of different types of treatment observers, and diagnosis and treatment in HIV-infected persons, among other topics. Research can help produce better diagnostic procedures and tests for detection of infection and disease; develop more effective vaccines and newer and more effective drugs; and also assist health planners in making optimal use of available tools and resources. Community-based research can help develop programmes specifically tailored to local needs and conditions.

DOTS has evolved through research conducted over decades

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in countries all over the world. It has truly been a collective effort. This spirit of partnership and collaboration will be key for an effective, sustained TB control programme in future years in India, particularly with the spectre of HIV and MDRTB on the horizon.

India's Revised National Tuberculosis Control Programme has important implications for the health and development of India. Not only can the RNTCP save millions of lives and hundreds of millions of dollars, it can also promote a culture in which decisions are based on data. This can provide a solid and lasting foundation for continuous improvement in India's health services.

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